

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

V.

Civil Action No. 04-12457 PBS

Arthrex, Inc.
a Delaware Corporation

Defendant.

**MEMORANDUM IN SUPPORT OF DEFENDANTS ARTHREX, INC.'S AND
PEARSALLS LTD.'S MOTION FOR SUMMARY JUDGMENT**

Dated: August 11, 2006

Charles W. Saber
Stephen A. Soffen
Salvatore P. Tamburo
DICKSTEIN SHAPIRO LLP
1825 Eye Street, N.W.
Washington, D.C. 20006-5403
Telephone: (202) 420-3116
Facsimile: (202) 420-2201

Christopher Weld, Jr. (BBO # 522230)
Raymond P. Ausrotas (BBO # 640315)
TODD & WELD LLP
28 State Street, 31st Floor
Boston, MA 02109
Telephone: (617) 720-2626
Facsimile: (617) 227-5777

Counsel for Defendants
Arthrex, Inc. and Pearsalls Ltd.

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION.....	1
II. STATEMENT OF FACTS.....	4
A. THE RELEVANT COMPANIES.....	4
B. ETHICON’S DEVELOPMENT WORK.....	4
C. THE ‘446 SPECIFICATION AND PROSECUTION HISTORY	5
D. ARTHREX’S DEVELOPMENT OF FIBERWIRE.....	7
III. ARGUMENT.....	7
A. STANDARDS FOR SUMMARY JUDGMENT.....	7
B. FIBERWIRE DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE ‘446 PATENT	8
1. The UHMWPE in FiberWire is not a yarn from the first set from the group consisting of PTPE, FEP, PFA PVDF, PETFE, PP AND PE.....	9
2. The Addition of Coating to FiberWire Avoids Infringement Because Coating Affects the Basic and Novel Characteristics of the ‘446 Patent	13
C. IF THE COURT CONSTRUES PE TO INCLUDE UHMWPE, THE ‘446 PATENT IS INVALID AS ANTICIPATED BY THE ‘575 PATENT	19
1. The ‘575 patent is prior art to the ‘446 patent	20
2. The ‘575 patent discloses every limitation of the asserted claims of the ‘446 patent	21
IV. CONCLUSION	27

TABLE OF AUTHORITIES

PageCases:

<i>AFG Indus., Inc. v. Cardinal IG Co., Inc.</i> , 239 F.3d 1239 (Fed Cir. 2001)-----	17, 18
<i>AK Steel Corp. v. Sollac and Ugine</i> , 344 F.3d 1234 (Fed. Cir. 2003)-----	13
<i>American Machine & Foundry Co. v. Liggett & Myers Tobacco Co.</i> , 172 F. Supp. 12 (D. N.J. 1959)-----	18
<i>Anderson v. Liberty Lobby, Inc.</i> , 477 U.S. 242 (1986)-----	8, 24
<i>Bayer A.G. v. Sony Electronics, Inc.</i> , 228 F. Supp.2d 332 (D. Del. 2002)-----	17
<i>Binney & Smith v. Rose Art Indus., Inc.</i> , 1995 U.S. Dist. LEXIS 2602 (N.D. Ill. 1995)-----	17
<i>Cooper v. Goldfarb</i> , 154 F.3d 1321 (Fed. Cir. 1998)-----	20
<i>Dynacore Holdings Corp. v. U.S. Philips Corp.</i> , 363 F.3d 1263 (Fed. Cir. 2004)-----	8, 9
<i>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.</i> , 344 F.3d 1359 (Fed. Cir. 2003)-----	10
<i>Free Motion Fitness, Inc. v. Cybex Intern, Inc.</i> , 423 F.3d 1343 (Fed. Cir. 2005)-----	13, 18
<i>Graver Tank & Mfg. Co. v. Linde Air Prods. Co.</i> , 339 U.S. 605 (1950)-----	10
<i>Hummer v. Administrator of Nat. Aeronautics and Space Admin.</i> , 500 F.2d 1383 (Ct. Cust. & Pat. App. 1974)-----	21
<i>Innovative Scuba Concepts, Inc. v. Feder Indus., Inc.</i> , 26 F.3d 1112 (Fed. Cir 1994)-----	20
<i>Invitrogen Corp. v. Clontech Laboratories, Inc.</i> , 429 F.3d 1052 (Fed. Cir. 2005)-----	22, 24
<i>London v. Carson Pirie Scott & Co.</i> , 946 F.2d 1534 (Fed Cir. 1991)-----	10
<i>Matsushita Elec. Indus. Co., Ltd. v. Cinram Int'l, Inc.</i> , 299 F.Supp.2d 348 (D. Del 1994)-----	8
<i>MicroStrategy, Inc. v. Business Objects, S.A.</i> , 429 F.3d 1344 (Fed. Cir. 2005)-----	8
<i>Moba, B.V. v. Diamond Automation, Inc.</i> , 325 F.3d 1306 (Fed. Cir. 2003)-----	19
<i>PPG Indus. v. Guardian Indus. Corp.</i> , 156 F.3d 1351 (Fed. Cir. 1998)-----	13
<i>Q-Pharma, Inc. v. Andrews Jergens Co.</i> , 360 F.3d 1295 (Fed. Cir. 2004)-----	8
<i>Scripps Clinic & Research Foundation v. Genentech, Inc.</i> , 927 F.2d 1565 (Fed. Cir. 1991)-----	19
<i>Slip Track Sys., Inc. v. Metal-Lite, Inc.</i> , 304 F.3d 1256 (Fed. Cir. 2002)-----	20
<i>Upjohn Co. v. Mova Pharmaceutical Corp.</i> , 225 F.3d 1306 (Fed. Cir. 2000)-----	11
<i>Warner-Jenkinson Co. v. Hilton Davis Chem. Co.</i> , 520 U.S. 17 (1997)-----	10, 11

Statutes

35 U.S.C. § 102(e)(2)-----	20
35 U.S.C. § 103-----	3
35 U.S.C. § 112-----	3

I. INTRODUCTION

In 2001, defendant Arthrex, Inc. (“Arthrex”) introduced a new suture, called FiberWire, for the orthopedic surgery market. Ex. 1 at 31:2-5. The new suture was more than twice as strong as the sutures conventionally used in orthopedic surgery. Ex. 2 at 8. The key ingredient of FiberWire, a “braided suture,” is ultra high molecular weight polyethylene (“UHMWPE”), one of the strongest synthetic materials that has ever been created. Ex. 3 at § 1.¹ Arthrex’s FiberWire suture was so new and revolutionary that it spawned a new category of suture called “high-strength” suture. Ex. 2 at 2; Ex. 4 at 146:7-14. Arthrex sells FiberWire separately, and it also includes FiberWire as a component of some of its suture anchors.

After seeing the impact of Arthrex’s FiberWire product, plaintiff DePuy Mitek, Inc. (“DePuy Mitek”) realized that without the introduction of its own high strength suture, it would not be able to meet its sales targets. Ex. 5. DePuy Mitek’s original idea was to introduce a “me too” suture that mimicked Arthrex’s FiberWire product. Ex. 5. Eventually, in late 2004, DePuy Mitek introduced its own high strength suture called Orthocord. Ex. 6. DePuy Mitek, however, was not content just to compete in the market. It searched its files to see if it owned some patent that it could assert against Arthrex. Although DePuy Mitek owned no such patents, it located a patent owned by Ethicon, Inc., a sister company that is a part of the Johnson & Johnson empire, and arranged to have the patent assigned to DePuy Mitek to assert it against Arthrex. Ex. 7.

This patent, U.S. Patent No. 5,314,446 (“the ‘446 patent”) (Ex. 8), resulted from a research effort by Ethicon in the late 1980’s and early 1990’s. The ‘446 patent is a paper patent; neither Ethicon nor DePuy Mitek has made a single commercial product under that patent. Ex. 9 at 9-10. Even in the laboratory, Ethicon did not build a sterilized surgical suture that falls within the claims of the patent before the filing date of the ‘446 patent. Ex. 10 at 346:7-10. Despite this

¹ The UHMWPE is braided together with a polyester known as PET.

enormous failure, DePuy Mitek now claims it is entitled to tens of millions of dollars in damages for infringement of this paper patent.

DePuy Mitek's effort to show infringement is a classic example of trying to fit a square peg into a round hole. Unlike Arthrex's FiberWire product, the '446 patent has nothing to do with a high strength suture. Quite to the contrary, the '446 patent, as explained in the specification, involves a combination of materials where a highly pliable and lubricious, but weak, material is added to a stronger material to improve the pliability and handleability aspects of the suture without appreciably sacrificing strength. Ex. 8 at col. 2, ll. 31-37, 62-66; col. 6, ll. 7-8. Even though the resulting suture would be weaker than conventional sutures, the pliability and handling advantages from adding the weak and pliable material outweighs any loss of strength.

Notwithstanding the teachings of the patent, DePuy Mitek asserts that FiberWire infringes. One of the highly pliable and lubricious, but weak, materials identified in the specification is polyethylene, denoted in the claims as "PE." According to DePuy Mitek, the claim term "PE" should be construed to include UHMWPE. The undisputed evidence, however, shows that UHMWPE is extraordinarily strong and a very stiff (non-pliable) material. Ex. 11 at ¶ 56; Ex. 12 at 306:20-307:4. As explained in more detail in the accompanying *Markman* brief ("*Markman Br.*"), DePuy Mitek can only make this argument by putting on blinders and ignoring the patent specification as well as the fundamental differences (e.g., function, molecular weight and molecular structure) between UHMWPE and the long known general purpose PE which had been used in sutures and other materials for decades. Ex. 13 at col. 11, l. 26. In sum, the term PE should properly be construed to exclude UHMWPE and accordingly, there is no infringement.

There is a second, independent reason why there is no infringement. The claims of the '446 patent all include the transitional phrase "consisting essentially of." As in all patent claims, the accused device must meet each and every limitation of the claim. But unlike many patent claims, there is no infringement of a "consisting essentially of" claim if the accused product includes additional ingredients that materially affect the "basic and novel characteristics" of the claimed invention. Here, Arthrex's FiberWire suture includes a coating. Ex. 14. The undisputed evidence in this case, including Ethicon's patents, a patent of DePuy Mitek's expert and the testimony of every relevant witness in this case, is that such coatings are added to sutures to improve the handleability aspects of the suture, especially the "knot tie down" characteristics of the suture. The inclusion of the coating on FiberWire is the death knell to any infringement claim. The stated purpose of the '446 patent was to improve the handleability aspects of the suture. Accordingly, the Arthrex coating affects the basic and novel characteristics of the claimed invention and thus, there is no infringement.²

Apart from the infringement inquiry, the claims of the '446 patent are invalid, particularly if the term "PE" is construed to include UHMWPE. As we show below, the prior art Chesterfield patent, U.S. Patent No. 5,318,575 ("the '575 patent") (Ex. 15), anticipates the claims of the '446 patent because every limitation of the claims is disclosed in that prior art patent (if the term "PE" is construed to include UHMWPE). DePuy Mitek's principal contention seems to be that the '575 patent is not prior art because Ethicon actually reduced its invention to practice before the filing date of that patent. The undisputed evidence, however, belies DePuy Mitek's contention. Ethicon built only a braid (which itself had significant problems), but never

² Arthrex has several other non-infringement arguments, but the above-identified arguments are its principal non-infringement contentions.

built a sterilized suture as required by the claims of the '446 patent. Accordingly, the '575 patent anticipates the claims of the '446 patent.³

II. STATEMENT OF FACTS

A. THE RELEVANT COMPANIES

Arthrex, a privately held Delaware corporation, develops and sells medical products in the field of arthroscopic surgery. Ex. 16. FiberWire is one such product. Pearsalls, a United Kingdom company, is a braid manufacturer. Pearsalls manufactures braids that eventually become FiberWire suture. DePuy Mitek, a Massachusetts corporation, and a Johnson & Johnson company, makes and sells medical products. Ex. 17. Ethicon, also a Johnson & Johnson company, makes and sells suture and was the original owner of the '446 patent. Ex. 18

B. ETHICON'S DEVELOPMENT WORK

Ethicon began the work that led to the '446 patent in 1988. As explained by inventor Steckel, this work was part of a larger project designed to examine possible suture improvements. Ex. 19 at. 103:23-104:17. At the time, the standard braided suture was a product called Ethibond, a suture made entirely of PET polyester which was braided to form the suture. Ex. 4 at 135:4-7.

Dr. Steckel's idea was to braid together two different substances, one to maintain as much of the strength of the suture as possible and the other to enhance the pliability (that is, bendability) and handleability of the suture. As Dr. Steckel explained, the goal was to produce a suture which maintained the strength of Ethibond (made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 19 at 103:23-104:17.

³ There are other prior art combinations that render the asserted claims of the '446 patent invalid for obviousness pursuant to 35 U.S.C. § 103, and the '446 patent is invalid for failing to meet the written description and enablement requirements of 35 U.S.C. § 112. These issues are not raised by this motion for summary judgment. Similarly, Ethicon committed inequitable conduct during the prosecution of the '446 patent which renders the patent unenforceable. This issue also is not raised by this motion.

In early 1989, Dr. Steckel built and tested several braids, although he did not build a sterilized suture, as set forth in the claims of the '446 patent. Ex. 19 at 225:5-8.⁴ Ethicon never built a sterilized suture before the filing date of the '446 patent. Ex.10 at 346:7-10. The braids that Dr. Steckel tested were made of PTFE (commonly known as Teflon) and PET (the polyester material used in Ethibond). Ex. 21 at DMI 2635-38. PTFE is a relatively weak substance, but is lubricious and quite pliable. PET, on the other hand, is a strong substance which gives the suture acceptable strength to avoid breakage. Ex. 8 at col. 4, ll. 33-40. While the resulting braid was not as strong as the all-PET control braid, Dr. Steckel observed that the increases in pliability (resulting from the lubricious PTFE) outweighed the loss of strength (caused by mixing the PET with the weaker PTFE). Ex. 8 at col. 8, ll. 36-49. Dr. Steckel observed that the prototype composite braid "ranked better than the silk and Ethibond in knot tie-down *even without a coating.*" Ex. 21 at DMI 2666. [Emphasis added.]

C. THE '446 SPECIFICATION AND PROSECUTION HISTORY

Three years after Dr. Steckel tested the braids, Ethicon filed the patent application that lead to the '446 patent. Ex. 8 at cover page. A full explanation of the '446 patent specification and prosecution history is included in the accompanying Markman brief (*see Markman Br.* at 2 - 6) and is summarized here as it relates to this motion. The specification teaches several things. First, lubricious yarns are too weak to use alone; that is, the suture would break. Ex. 8 at col. 2, ll. 22-25; col. 4, ll. 50-54; Table. Second, the lubricious yarns are highly pliable, that is, they are very easy to bend. Ex. 8 at col. 2, ll. 22-25; col. 4, ll. 11-14; Table. Third, using two different materials braided together is designed to improve the handleability and pliability aspects of a suture without significantly sacrificing the overall braid strength. Ex. 8 at

⁴ Even here, the braids had considerable problems of "core popping," a problem exacerbated by the difficulties presented by attempting to braid together two different materials. More than a year later, Ethicon observed that the problem had not been solved. Ex. 20. There is no evidence that the problems were ever solved. Ex. 19 at 251:24-252:5.

col. 2, ll. 31-37; ll. 62-66; col. 4, ll. 11-40; col. 6, ll. 7-8. Fourth, while adding coating to a braid is helpful for knot tie down (a handleability characteristic), it creates problems with pliability (as well as added costs). The use of coating can be avoided, and the downsides it brings can be eliminated if a sufficient amount of the lubricious material is used. Ex. 8 at col. 6, ll. 5-17.

The pertinent aspects of the prosecution history can be summarized as follows. As originally filed, the application included claims directed toward “braids” and others directed toward “sutures.” Ex. 22 at 18-20. In response to the Examiner’s assertion that “braid” claims and “suture” claims were different, Ethicon agreed only to prosecute the suture claims. Ex. 23 at 3. In response to a rejection of the claims based on the U.K. patent application to Burgess (“the Burgess application”), Ethicon argued that the qualities of UHMWPE would lead to a poor suture, a clear assertion that Ethicon did not believe that UHMWPE was a material that fell within the patent claims. Ex. 24 at 2-4. In addition, the claims were amended during prosecution to limit significantly the scope of the claims. The transitional phrase “comprising” was amended to “consisting essentially of,” a significantly narrower claim. Ex. 25 at 1. The claims were also narrowed by abandoning the requirement that the suture may be made of two “dissimilar yarns” and instead requiring that the two yarns be from a two lists of specified materials (one from each list). Ex. 25 at 1.

In the claims, seven polymers are identified as the yarns in the first group, of which “PE” is one. As explained in the specification, these materials are lubricious and highly pliable, but are too weak to be used alone. Ex. 8 at col. 2, ll. 22-25; col. 4, ll. 9-32, 50-54; Table. Three materials, PET, nylon and aramid, are identified in the second group. According to the specification, these materials are added to strengthen the suture. Ex. 8 at col. 4, ll. 33-40. Notably, the term PE is never associated with the “strength” yarns.

D. ARTHREX'S DEVELOPMENT OF FIBERWIRE

In the late 1990's, Arthrex investigated the development of a new suture product.⁵ Its motivation was to develop a suture much stronger than existing sutures in the market, one which would be less likely to break when used in orthopedic surgery. Ex. 26 at 44:13-46:9. The original idea was to make a braided suture entirely of UHMWPE, a material known for its incredible high strength. Ex. 26 at 44:13-46:9. While the prototypes met the strength criteria, there were some problems. The suture was too stiff, that is, it lacked pliability, and was difficult to use. Ex. 12 at 306:20-307:4. In addition, while the knots were strong and did not break, the knots had a tendency to slip, making it difficult to secure the knot. Ex. 26 at 46:7-9. The solution was to add PET (the polyester that was used in existing sutures) to the suture braid. The PET was added to provide better flexibility to the suture and to improve the knot security of the suture. Ex. 26 at 68:25-69:21. FiberWire also adds a coating to improve the ability for the knot to slide down the suture and other handleability aspects of the suture. Ex. 14.⁶ Arthrex introduced FiberWire as a stand alone product in August 2001 and eventually began offering FiberWire as an option on most of its suture anchor products. Ex. 27.⁷

III. ARGUMENT

A. STANDARDS FOR SUMMARY JUDGMENT

Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a

⁵ At the time, Arthrex did not sell suture as a separate product. It did attach sutures, which it bought from an outside vendor, to the suture anchors that it sold.

⁶ As an added benefit, the coating improves the strength of the knot and the pliability of the suture.

⁷ Arthrex also sells variants of FiberWire, called TigerWire and FiberStick. For the purposes of this motion, the differences between the products is not relevant. Accordingly, the term "FiberWire" in this motion includes FiberWire and its variants.

matter of law. *Q-Pharma, Inc. v. Andrews Jergens Co.*, 360 F.3d 1295, 1299-1300 (Fed. Cir. 2004). The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor. *Id.*

The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. *Matsushita Elec. Indus. Co., Ltd. v. Cinram Int'l, Inc.*, 299 F.Supp.2d 348, 357 (D. Del. 1994) (citing to *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986)). If the nonmoving party fails to make a sufficient showing of an essential element of its case with respect to which it has the burden of proof, then the moving party is entitled to judgment as a matter of law. *Id.* (citing to *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). In other words, the court must grant summary judgment if the party responding to the motion fails to make a sufficient showing on an essential element of his case with respect to which he has the burden of proof. *Id.* at 357.

B. FIBERWIRE DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '446 PATENT

To establish infringement, the plaintiff must show that the accused product has each and every limitation of the asserted claim either literally or by the doctrine of equivalents. *See, e.g., Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1273 (Fed. Cir. 2004). If even a single limitation is missing in the accused product, there is no infringement.

MicroStrategy, Inc. v. Business Objects, S.A., 429 F.3d 1344, 1352 (Fed. Cir. 2005). Claim 1, cited in full below,⁸ is an independent claim. The other asserted claims, claims 2, 8, 9 and 12,

⁸ Claim 1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

are dependent claims, that is, they include all the limitations of the independent claim (here claim 1) plus additional limitations. Since the two infringement defenses presented in this motion relate to limitations in the independent claim, they also relate to limitations in the dependent claims.

There are at least two reasons why there is no infringement of the asserted claims. First, the FiberWire product does not have “PE,” as that term should be construed within the patent. Second, the addition of coating to the FiberWire product eliminates any possibility of infringement because coating affects the basic and novel characteristics of the ‘446 patent.

1. The UHMWPE in FiberWire is not a yarn from the first set from the group consisting of PTPE, FEP, PFA PVDF, PETFE, PP AND PE
 - a. There is no literal infringement

The infringement inquiry is a two part process. First, the claim terms must be properly construed and second, a determination must be made whether the accused device has the properly construed limitations. *Dynacore Holdings*, 363 F.3d at 1273. There is no dispute that FiberWire contains UHMWPE. It is DePuy Mitek’s position that UHMWPE constitutes “PE” and thus, the “yarn from the first set” limitation is met. But as we show in our *Markman* brief, the proper construction of “PE” excludes UHMWPE. *See Markman Br.* at 10-16. Should the Court agree, then there is no dispute that FiberWire does not contain any of the identified “yarn[s] from the first set” and accordingly, there is no literal infringement of the asserted claims.

- b. There is no infringement under the doctrine of equivalents

DePuy Mitek contends that even if this Court construes the term “PE” to exclude UHMWPE, there is still infringement under the doctrine of equivalents. Infringement by

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid, and c) optionally a core.

equivalents is a limited doctrine designed to prevent “[o]ne who seeks to pirate an invention [by making] minor variations to conceal and shelter the piracy.” *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950). Application of the doctrine of equivalents should be the exception, not the rule because, if the doctrine becomes simply the second prong of every infringement charge, claims will cease to serve their intended notice purpose. *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed Cir. 1991). Accordingly, infringement by equivalents can only be found if the differences are insubstantial. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997).

The doctrine of equivalents is further limited by the “all elements” rule. This means that equivalents must be applied to individual elements of the claim rather than to the invention as a whole. *Id.* at 18.⁹ Thus, the question is whether the differences between UHMWPE and the first set of yarns is insubstantial. Unless that test is met, there can be no equivalents.

The undisputed facts show that UHMWPE is not equivalent to the materials identified in the first set of yarns. Indeed, for the same reasons that UHMWPE does not fall within the meaning of PE, UHMWPE cannot be considered an equivalent. The first set of yarns constitute lubricious yarns included in the braid “to improve overall pliability” of the suture. Ex. 8 at col. 4, ll. 12-13. A braid made solely of such lubricating yarns is described as “highly pliable.” Ex. 8 at col. 2, ll. 23-24. UHMWPE is stiff (Ex. 12 at 306:20-307:4) and as DePuy Mitek’s expert admits, a braid made of only UHMWPE is too stiff (Ex. 11 at ¶ 56) – the polar opposite of what is described in the ‘446 patent.

⁹ The doctrine of equivalents is further limited by prosecution history estoppel which, except under limited circumstances, prevents a finding of equivalents if the claim limitation was amended. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd.*, 344 F.3d 1359, 1366 (Fed. Cir. 2003). Here, the first set of yarns limitation was added by amendment, so prosecution history estoppel precludes a finding of equivalents. This issue, however, is not presented by this motion.

Likewise, the admitted purpose of using UHMWPE in FiberWire is to add strength to the braid (Ex. 11 at ¶ 56; Ex. 28 at 290:19-25). In the '446 patents, the purpose of the first set of yarns is to improve pliability and handleability. It is the second set of yarns that imparts strength in the '446 patent.

Finally, the '446 patent teaches that lubricating yarns are "relatively weak." Ex. 8 col. 2, l. 25. In the tradeoff between braid strength and pliability, the '446 patent accepts the fact that the first set of yarn will somewhat weaken the braid because the increases in pliability from the first set of yarns will outweigh the loss of strength. Ex. 8, col. 2, ll. 26-28, 31-37; col. 8, ll. 19-49. The undisputed facts are that UHMWPE is strong, not weak. In light of these undisputed differences, the only possible conclusion is that the differences between the first set of yarns and UHMWPE is not insubstantial and accordingly, there can be no infringement by equivalents.

DePuy Mitek's attempts to create an equivalent argument where one does not exist through the report and testimony of its expert, David Brookstein. Dr. Brookstein uses a "function, way, result" test¹⁰ and concludes that UHMWPE is equivalent to the first set of yarns.¹¹ The function, way, result test is met if the function, way and result set forth in the patent for the limitation at issue (here, the first set of yarns) is the same as the function, way and result of the alleged equivalent material (UHMWPE). *Upjohn Co. v. Mova Pharmaceutical Corp.*, 225 F.3d 1306, 1309 (Fed. Cir. 2000).

The analysis that Dr. Brookstein sets forth, however, bears no relationship to the claims. For example, according to Dr. Brookstein, "[t]he function of the first set of yarns is to

¹⁰ The function, way result test can be used to decide the equivalents issue in appropriate cases. *Warner-Jenkinson*, 520 U.S. at 39-40.

¹¹ Dr. Brookstein could not decide at his deposition whether UHMWPE should be compared to the first set of yarns or just to PE. Ex. 29 at 276:11-15; 279:1-20. His report, however, makes the comparison to the first set of yarns.

contribute a property that is different from the second set.” Ex. 11 at ¶ 54. But Dr. Brookstein was forced to admit that *any* material would meet his functional identify as long as it contributed *anything* to the suture different from the second yarn. Ex. 28 at 285:4-10. Just to state the proposition is to demonstrate the absurd and unsupportable nature of the Brookstein test.

The simple fact is that the Brookstein recitation of function bears no relationship to the function of the first set of yarns set forth in the claims, as the law requires. The first set of yarns is comprised of the seven specific materials set forth in the claims. The patent leaves no doubt that a function of those materials is “to improve the overall pliability” of the braid. Ex. 8 at col. 4, ll. 12-13. The UHMWPE in FiberWire, of course, does not serve that function. It cannot because, as even Dr. Brookstein admits, it is too stiff. Ex. 11 at ¶ 56.¹² On this basis alone, the Brookstein analysis is fatally flawed.¹³

The prosecution history of the patent further reveals the flaw in Dr. Brookstein’s analysis. As the application was originally filed, it included broad claims which required only that there be two dissimilar yarns in direct intertwining contact. These original claims did not identify any specific materials. Ex. 22 at 18-20. But Ethicon abandoned these claims and instead only pursued the narrower claims which did identify the specific materials in each set of yarn. Ex. 25. While an argument could be made that Dr. Brookstein’s function and result have some relationship to these broad, abandoned claims, his analysis simply ignores the fact that these claims are not the claims at issue here. Dr. Brookstein admitted that he never considered the prosecution history in performing his function, way, result test. Ex. 28 at 289:15-23. If he

¹² Indeed, even Dr. Brookstein admits that the “flexibility,” *i.e.*, pliability function is served by the PET, not UHMWPE, in FiberWire. Ex. 11 at ¶ 64; Ex. 28 at 300:24-301:15.

¹³ Dr. Brookstein’s analysis of the “result” comparison suffers from the exact same problem. Ex. 11 at ¶¶ 61-63.

had, he would have realized that the function and result set forth in his report have no relationship to the function and result of the first set of yarns, as claimed in the '446 patent.

2. The Addition of Coating to FiberWire Avoids Infringement Because Coating Affects the Basic and Novel Characteristics of the '446 Patent

Patent claims typically include a transition phrase between the preamble of the claim and the rest of the claim. Most often, that transitional phrase is “comprising.” This means that the patent claim is “open”, that is, infringement is not avoided where the accused device includes materials in addition to those identified in the claim. *See, e.g., Free Motion Fitness, Inc. v. Cybex Intern, Inc.*, 423 F.3d 1343, 1353 (Fed. Cir. 2005). Unlike the phrase “comprising,” the phrase “consisting essentially of” in a patent claim is not an open term. Infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel properties of the claimed invention. *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). In this case, it is undisputed that FiberWire includes a coating, and that coating is not a listed item in the asserted claims. Thus, the sole issue is whether coating materially affects the basic and novel characteristics of the claims of the '446 patent. The undisputed facts show that it does and accordingly, there is no infringement.

The first step is to define the basic and novel characteristics of the claims of the '446 patent. This issue is discussed in detail in the *Markman* brief. *See Markman Br.* at 16-18. The second step is to determine whether coating materially affects those basic and novel characteristics.¹⁴ As we show below, the undisputed facts are that it does.

As shown in our *Markman* brief, the basic and novel characteristics of the claims of the '446 patent is having two dissimilar yarns braided together to achieve improved handleability or pliability without significantly sacrificing its physical properties. *See Markman Br.* at 16-18.

¹⁴ An effect on the basic and novel characteristics of the claimed invention is material if the affect is of importance or of consequence to those of ordinary skill in the art. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

The evidence overwhelmingly and undisputedly shows that coating materially affects the handleability aspects of the suture,¹⁵ particularly the knot tie down characteristics.¹⁶

That coating affects handleability characteristics of the braid, including knot tie-down, is so well known in the suture art that it hardly bears citation.

(1) Ethicon patent after Ethicon patent, including patents of Alistair Hunter, one of the inventors of the '446 patent, make that statement. *See* Ex. 34, col. 1, ll. 14-18 (“a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture”); Ex. 35, col. 1, ll. 11-15 (same); Ex. 36, col. 1, ll. 12-15 (“multifilament suture typically require a surface coating to improve the pliability and knotting characteristics of the suture”).

(2) A patent of Dr. Matthews Hermes, one of DePuy Mitek’s experts in this case, makes the same assertion. Ex. 37, col. 1, ll. 19-25 (“It has therefore become a common practice to coat sutures, particularly those of the multifilament variety, with compositions which improve their knot tie-down performance and perhaps one or more other properties of the sutures as well”).

¹⁵ There is also significant evidence that coating affects the pliability of the suture as well as knot strength. Those issues, however, are not raised by this motion.

¹⁶ As Ethicon’s own Wound Closure Manual explains, knot tie down is the ease by which a knot slides down the suture. Ex. 29. A drawback of a braided suture is that it can be relative rough. As a result, when a surgeon slides a knot down the suture, the roughness may cause some “chatter” making it more difficult to tie a knot. Ex. 30 at col. 1, ll. 43-54. As DePuy Mitek and Ethicon witnesses observe, knot tie down is a well known suture handleability characteristic. Ex. 31 at 165:16-166:3; Ex. 32 at 94:19-95:6; Ex. 19 at 79:19-23. In fact, the ‘446 patent itself recognizes knot tie down as a handleability characteristic of a suture. Ex. 8 at col. 6, ll. 5-7.

Likewise, other known handleability characteristics include tactile feel, compliance, tissue drag, knot security, knot stability, coefficient of friction, stiffness, softness, smoothness, lack of chatter, tissue abrasion and lie-down of the knot. Ex. 33 at 20.

(3) Ethicon's Wound Manual makes the same point. Ex. 29 at 11 ("Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics.").

(4) Articles in the field concur. *See* Ex. 28 at 525 ("synthetic sutures have been coated to decrease their coefficient of friction and improve their handling characteristics.").

(5) Ethicon and DePuy Mitek observed that coating affects handleability when developing its Orthocord product (which competes directly with FiberWire) and other suture products. *See, e.g.*, Ex. 39 (Orthocord is coated "for improved slide ability and enhanced knot tying characteristics (*e.g.* knot slide)."); Ex. 40 ("The purpose of coating the Panacryl suture is to provide the suture with handling properties.").

(6) Every DePuy Mitek and Ethicon witness who testified on the subject agreed. Ex. 4 at 64:12-24; Ex. 41 at 48:11-49:2; Ex. 31 at 167:1-13; Ex. 18 at 295:23-296:7; Ex. 42 at 63:10-23.¹⁷

In light of this overwhelming evidence, it comes as no surprise that Arthrex's documents confirm that coating is added to improve handling characteristics. *See* Ex. 14 ("The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue). And if there were any doubt – and there is absolutely none, the '446 patent itself confirms that coating is added to improve handling characteristics of the suture, including knot tiedown *See* Ex. 8 at col. 1, ll. 29-31 ("multifilament sutures almost universally possess a

¹⁷ Incredibly, the only witness who did not readily agree was Dr. Brookstein, DePuy Mitek's so-called suture expert. When confronted with this overwhelming evidence, Dr. Brookstein's meek response was that had not reviewed the material (although he had had the opportunity to do so) and that he simply does not know if this is the known purpose of adding a coating. Ex. 28 at 167:14-169:6. The only conclusion that can be drawn from his testimony is either that Dr. Brookstein is not an expert on suture coating (a likely conclusion because he testified that he only worked on one suture project in his professional life and he did not remember if it involved issues of coating (Ex. 28 at 165:16-166:4)) or Dr. Brookstein simply cannot be believed.

surface coating to improve handling properties.”); col. 6, ll. 5-8 (“If desired, the surface of the heterogeneous multifilament braid can be coated . . . to further improve the handleability and knot tiedown performance of the braid.”).

In short, the evidence is overwhelming and cannot be disputed. Coating affects the handleability of the suture – the same suture improvement that the ‘446 patent purports to achieve by its invention. Since the undisputed facts are that coating is added to FiberWire and coating materially affects the basic and novel characteristics of the claimed invention, there is no infringement.¹⁸

DePuy Mitek has no answer to this daunting evidence, so it incorrectly tries to change the question. According to its expert Dr. Brookstein, DePuy Mitek argues as follows: FiberWire was designed to have the two different yarns – UHMWPE and PET – contribute different properties to the braided suture. The contribution of different properties is present both before and after coating is added. Therefore, coating does not materially affect the basic and novel characteristics of the claimed invention. Ex. 44 at ¶ 24. DePuy Mitek comes to the same conclusion both under its and defendants’ view of the basic and novel characteristics of the claimed invention. Ex. 44 at ¶ 23.

¹⁸ The result is no different if the court were to accept DePuy Mitek’s view of the basic and novel characteristics of the claimed invention. According to DePuy Mitek, the basic and novel characteristics are “a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. *See* Ex. 11 at ¶ 27; *see also* Ex. 44 at ¶ 28. As we understand DePuy Mitek’s position, it does not matter what property each yarn contributes to the suture, an added, unlisted material – here coating – affects the basic and novel characteristics as long as it affects the same suture property as one of the yarns.

PET is one of the yarns of the FiberWire braid. As DePuy Mitek itself contends, one of the purposes of the PET is to improve the knot tying ability of the suture braid. *See* Ex. 45 at ¶ 15. As shown above, this is one of the precise purposes of coating a suture. *See supra* at 13-16. Accordingly, even under DePuy Mitek’s view of the basic and novel characteristics of the claimed invention, coating has a material effect and its inclusion in FiberWire precludes a finding of infringement.

Stated another way, Dr. Brookstein asserts that coating does not affect the basic and novel aspects of the claimed invention because “the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided.” Ex. 44 at ¶ 27. When asked what this means, Dr. Brookstein replied that coating could only affect the basic and novel characteristics if “the coating in some *miraculous* way made those materials not yarns anymore” or “all of a sudden you had a set from A, a set from B and now it was some magical structure that wasn’t yarns, it wasn’t two sets, they were all the same, that would be a transformation.” Ex. 28 at 399-400, emphasis added. Just to state the proposition shows its absurdity. In DePuy Mitek’s and Dr. Brookstein’s world, only “magic” and “miracles” can cause an added material to affect the basic and novel characteristics of an invention. That plainly is wrong.

The most that could be said of DePuy Mitek’s position is that it believes that an added material that improves the basic and novel characteristics can never materially affect those characteristics, no matter how much the improvement. Indeed, Dr. Brookstein opined that coating could never affect the basic and novel characteristics even if it “improves one of the properties that one of the materials contributes to the braid.” Ex. 28 at 211:7-14. But the law is to the contrary. The Federal Circuit acknowledged that an added material can affect the basic and novel characteristics of an invention even if it only serves to improve those characteristics. *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1246 (Fed Cir. 2001) (citing witness testimony that barrier layers are necessary for operation of accused product). *See also, Bayer A.G. v. Sony Electronics, Inc.*, 228 F. Supp.2d 332, 346-47 (D. Del. 2002) (stating that presence of cobalt materially affected the basic and novel properties of the claimed invention while citing witness testimony that the affect was to improve those properties); *Binney & Smith v. Rose Art Indus., Inc.*, 1995 U.S. Dist. LEXIS 2602 at *30 (N.D. Ill. 1995) (in denying injunctive relief due

to unlikelihood of success on infringement, court cited advantages of large volume of silicon dioxide in accused product as potential material affect); *American Machine & Foundry Co. v. Liggett & Myers Tobacco Co.*, 172 F. Supp. 12, 19 (D. N.J. 1959) (stating improvements in water resistance were material affect of basic and novel characteristics).

DePuy Mitek's second argument is that coating cannot affect the basic and novel characteristics of the claimed invention because the '446 patent says that "if desired, the surface of the . . . braid can be coated . . . to further improve the handleability and knot tiedown performance of the braid." Ex. 44 at ¶ 33. Depuy Mitek is wrong for several reasons. The short answer is that the law is to the contrary. In *AFG*, just like here, the patent stated that certain materials could be added. *AFG*, 239 F.3d at 1242. Notwithstanding that disclosure, the Federal Circuit acknowledged that use of such unlisted materials could materially affect the basic and novel characteristics of the invention. *AFG*, 239 F.3d at 1247. *See also, American Machine*, 172 F. Supp. at 19 (although additional substances were disclosed in specification, they were not in claims and could materially affect basic and novel characteristics).

Even if DePuy Mitek's argument had applicability in some circumstances, it would not apply here. As explained above, the claims, as originally submitted did not contain the "consisting essentially of" transitional phrase. Rather, the transitional phrase in the original claims was "comprising." For a "comprising" claim, it is no defense that the accused product has additional unlisted materials. *Free Motion*, 423 F.3d at 1353. Accordingly, it makes perfect sense, as the application was originally filed, that the patent would state that coating could be used, particularly because the patent recognizes that the coating improves certain handleability aspects of a suture. But once the transitional phrase "consisting essentially of" was added to the claim, which in turn narrowed the claim, DePuy Mitek's rationale falls apart.

Finally, an accurate reading of this passage of the patent shows that it supports *defendants'* position, *not* DePuy Mitek's. The passage asserts that coating improves suture handleability and knot tiedown, itself an *admission* that coating affects the basic and novel characteristics. The passage goes on to say that "if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, *the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening*." Ex. 8 at col. 6, ll. 13-17, emphasis added. That the patent teaches it is best to "eliminate[]" and "avoid[]" coating is graphic proof that its use in the accused product should lead to a finding of no infringement. *See, e.g., On Demand Machine Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1340 (Fed. Cir. 2006) (claims may be construed to exclude a feature criticized in the specification).

For all the foregoing reasons, use of coating in FiberWire affects the basic and novel characteristics of the patent and, as a result, there is no infringement.

C. IF THE COURT CONSTRUES PE TO INCLUDE UHMWPE, THE '446 PATENT IS INVALID AS ANTICIPATED BY THE '575 PATENT

As explained in detail in Defendants' *Markman* brief, properly construed, the claim term "PE" means a general purpose polyethylene and does not include UHMWPE. If, however, the Court were to determine that the claim term PE does include UHMWPE, then the '446 patent is invalid as anticipated by the '575 patent.

A patent claim is invalid for anticipation where a single prior art reference discloses every limitation of the patent claim. *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1321 (Fed. Cir. 2003). As long as the claimed invention is disclosed within the "boundaries of a single reference," the reference anticipates. *See, e.g., Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1577 (Fed. Cir. 1991). As we show below, the '575 patent is prior art to the '446 patent and, if PE is construed to include

UHMWPE, every limitation of the asserted claims of the ‘446 patent is disclosed within “the boundaries of” the ‘575 patent.

1. The ‘575 patent is prior art to the ‘446 patent

On its face, the ‘575 patent is prior art to the ‘446 patent under 35 U.S.C. § 102(e)(2) since it was filed prior to the filing date of the ‘446 patent.¹⁹ The only way DePuy Mitek can show that the ‘575 patent is not prior art is by providing evidence that it invented the subject matter of the ‘446 patent prior to the filing date of the ‘575 patent (*i.e.*, February 3, 1992). *See e.g., Innovative Scuba Concepts, Inc. v. Feder Indus., Inc.*, 26 F.3d 1112, 1115 (Fed. Cir 1994) (burden of going forward with evidence of prior invention shifts to patentee once evidence of prior art is presented by defendant). In order to show it invented the subject matter of the ‘446 patent prior to the filing date of the ‘575 patent, DePuy Mitek must show that the claimed invention of the ‘446 patent was both conceived of and reduced to practice prior to the filing date of the ‘575 patent. *Id.*

According to its interrogatory answers and its expert submissions, DePuy Mitek argued that it can predate the ‘575 patent because Ethicon conceived of the invention by June 6, 1988 and reduced it to practice by February 1989. The undisputed facts, however, establish that Ethicon did not reduce the invention to practice prior to the date that it filed its patent application.

To establish reduction to practice, DePuy Mitek “must prove that [it] constructed an embodiment . . . *that met all the limitations of the claim*, and that [it] determined that the invention would work for its intended purpose.” *See e.g., Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002). [Emphasis added.] *See also, Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998) (“there cannot be a reduction to practice of the invention

¹⁹ The ‘575 patent was filed February 3, 1992, whereas the ‘446 patent was filed February 19, 1992. *Compare* Ex. 15 at cover page, Ex. 8 at cover page.

without a physical embodiment which includes all limitations of the claim”), *Hummer v. Administrator of Nat. Aeronautics and Space Admin.*, 500 F.2d 1383, 1387 (Ct. Cust. & Pat. App. 1974) (“to constitute an actual reduction to practice, the device demonstrated must include every limitation of the claim”) Thus, if even a single claim limitation is missing from what is built, there is no reduction to practice.

The undisputed evidence in this case is that Ethicon, through its inventor, Dr. Steckel, built and tested heterogeneous braids in February 1989. But one of the limitations of the asserted claims is that the product be a *sterilized* suture. The undisputed evidence is that the braids built and tested by Dr. Steckel were not “sterilized.” Dr. Steckel’s notebook makes no mention of sterilization in connection with any work on this project and Dr. Steckel confirmed that the heterogeneous braids he tested were not sterilized. Ex. 19 at 225:5-8. Likewise, Dr. Hermes confirmed that he had no evidence that Ethicon built a sterilized suture before the filing date of the ‘446 patent. Ex. 10 at 346:7-10.

Since, as a matter of law, reduction to practice requires that the embodiment constructed meet *all* the limitations of the claim, and since it is undisputed that the braids constructed by Dr. Steckel were not “sterilized,” a limitation of all the asserted claims of the ‘446 patent, DePuy Mitek can not predate the ‘575 patent by showing an earlier reduction to practice. Accordingly, the ‘575 patent is prior art to the ‘446 patent.

2. The ‘575 patent discloses every limitation of the asserted claims of the ‘446 patent

As explained above (*supra* at 19), a patent claim is anticipated where a single prior art reference discloses every limitation of the claim. As we show below, every limitation of the asserted claims of the ‘446 patent is disclosed in the ‘575 patent.

- a. Independent claim 1 is anticipated by the ‘575 patent

For the convenience of the Court, we break down claim 1 of the '446 patent into its various limitations, and then we demonstrate that each limitation is disclosed in the '575 patent.

i. A surgical suture consisting essentially of

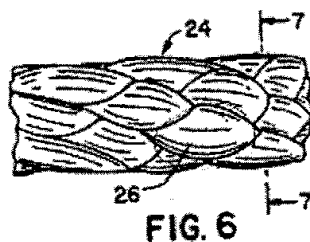
The '575 patent discloses a surgical suture. For example, the title of the '575 patent itself recites a method of using a "suture product." Since the '575 patent is directed to suture, it should come as no surprise that sutures are disclosed many times in connection with the '575 patent specification and drawings. Ex. 15 at col. 2, l. 62; col. 3, ll. 2, 8, 15; col. 7, l. 26, 38, 43, 59.

Incredibly, DePuy Mitek, through its expert Dr. Hermes, tries to raise a factual dispute. Although Dr. Hermes conceded in his report that claim 1 of the '575 patent recites "a flexible elongated member," he stated that it was his "opinion" that this was limited to a sternum closure device and not a suture. Ex. 43 at ¶ 80. But Dr. Hermes simply ignores the disclosure of the '575 patent continually describing the elongated member as a suture. Moreover, when confronted with this evidence at his deposition, Dr. Hermes had no choice but to admit that the '575 patent does disclose flexible elongated members that are sutures. Ex. 10 at 212:25-213:5. Accordingly, Dr. Hermes's "opinion" is not supported by any factual basis and cannot create a dispute over a genuine issue of material fact. *See, e.g., Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052, 1080-81 (Fed. Cir. 2005) (without a foundation or basis for an expert's opinion, that opinion alone does not rise to the level of "genuine issues of fact" to defeat a motion for summary judgment).

- ii. a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

The next limitation of claim 1 of the '446 patent is also disclosed by the '575 patent. For example, claim 1 of the '575 patent recites that "first and second fibers" are "braided to form [an] elongated member." A person of ordinary skill in the art would plainly understand that this is a disclosure of two materials braided together in direct intertwining contact. See Mukherjee Rebuttal Report at 9. Even DePuy Mitek's expert meant "direct intertwining contact" when he used the term "braided" in his own patent. Ex. 45 at col. 2, l. 65 – col. 3, l. 2; Ex. 10 at 170:6-12.

Further, FIG. 6 of the '575 patent (reproduced below) discloses a spiroid braid with several yarns (items 26) that are braided in "direct intertwining contact," according to the construction agreed upon by the parties.



That is, FIG. 6 discloses that there is a "mechanical interlocking or weaving of the individual yarns [items 26] that make up the suture braid." Even Dr. Hermes agreed that FIG. 6 disclosed direct intertwining contact. Ex. 10 at 201:24-202:5.²⁰

DePuy Mitek has not attempted to contest that the vast majority of this limitation is disclosed in the '575 patent. The only aspect with which it attempts to take issue is the requirement that the one yarn from the first set is "in direct intertwining contact" with at least one yarn from the second set. According to DePuy Mitek, through its expert Dr. Hermes, the

²⁰ Furthermore, the disclosure of the '575 patent also acknowledges that the suture products must be sterilized. Ex. 15 at col. 1, line 36 (citing U.S. Patent No. 4,813,416, which discloses the need for sterilization with surgical products).

‘575 patent does not show any “direct intertwining contact” between the two different materials, one from each of the sets of yarns described in the ‘446 patent.²¹

In his report, Dr. Hermes opined that the claims of the ‘575 patent “do not recite that the first and second fibers are in direct intertwining contact, as opposed to a core-sheath arrangement.” Ex. 43 at ¶ 79. But, at his deposition, Dr. Hermes could not provide a single example of a braided construction that was not braided in “direct intertwining contact.” Ex. 10 at 212:25-213:5. Further, when confronted with the spiroid braid in FIG. 6 of the ‘575 patent (reproduced above), Dr. Hermes admitted that it disclosed “direct intertwining contact.” Ex. 10 at 201:24-202:5.

In short, there is absolutely no legitimate factual basis for Dr. Hermes’s opinion. The Federal Circuit has held that without a foundation or basis for an expert’s opinion, that opinion alone does not rise to the level of “genuine issues of fact” to defeat a motion for summary judgment. *Invitrogen*, 429 F.3d at 1080-81. The court also stated that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. *Id.* at 1080 (citing the Supreme Court in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986)). Likewise, here, DePuy Mitek has not raised a genuine issue of material fact.

- iii. a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

²¹ The only other place DePuy Mitek appears to contest the sufficiency of the disclosure of the ‘575 patent is in its response to Arthrex’s interrogatories. There, DePuy Mitek only contends that “Arthrex has failed to cite to a teaching of braided yarns as claimed in the ‘446 patent. Ex. 46. No reasoning or evidence is provided. A conclusion without support cannot raise a genuine issue of disputed fact. *See, e.g. TechSearch, L.L.C. v Intel Corp.*, 286 F.3d 1360, 1372 (Fed. Cir. 2002). Thus, this interrogatory response cannot create a genuine issue of material fact.

This limitation of claim 1 of the '446 patent is also disclosed by the '575 patent. For example, claim 1 of the '575 patent recites that the first fibers are "ultra high molecular-weight high tenacity material." The specification of the '575 patent specifically discloses that the ultra high molecular-weight high tenacity material is UHMWPE. Ex. 15 at col. 2, l. 31.

DePuy Mitek does not dispute this limitation. In fact, Dr. Hermes agreed that "ultra high molecular high tenacity material," as recited in claim 1 includes UHMWPE. Ex. 10 at 197:12-25

- iv. b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

This limitation of claim 1 of the '446 patent is also disclosed by the '575 patent. For example, claim 11 of the '575 patent adds that the second fiber is nylon.

Although the '575 patent need disclose only one of these materials in this limitation to anticipate, it does disclose another material. For instance, claim 12 of the '575 patent adds that the second fiber is polyester.²²

DePuy Mitek does not dispute these disclosures. In fact, Dr. Hermes acknowledged these disclosures in the '575 patent at his deposition. Ex. 10 at 198:7-11, 14-18.

- v. c) optionally a core

Since this last limitation is optional, the '446 patent need not disclose it for the '575 patent to anticipate the '446 patent.

- b. The asserted dependent claims of the '446 patent are anticipated by the '575 patent

²² The specific polyester identified in the '575 patent is Dupont Dacron polyester (*i.e.*, a trade name for PET). Ex. 15 at col. 7.1.63. Moreover, DePuy Mitek's expert Dr. Brookstein asserted that polyester is synonymous with PET to those skilled in the suture art. Ex. 28 at 54:4-9.

The additional limitations added by the asserted dependent claims are also shown in the ‘575 patent.²³ Asserted claim 2 of the ‘446 patent adds that the suture is attached to a needle. The ‘575 patent also discloses the use of a needle attached to a suture. Ex. 15 at col. 5, ll. 41-42.

Asserted claim 8 of the ‘446 patent also adds that the second fiber-forming material is PET. As described, in n. 22, *supra*, the specific polyester identified in the ‘575 patent is Dupont Dacron polyester (i.e., a trade name for PET). Ex. 15 at col. 7, l. 63.²⁴

Asserted claim 9 also adds the PET requirement (the additional limitation from claim 8) and further adds that “the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.” As stated in the *Markman* brief, the parties have agreed that this claim term means that “the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture” ranges from about 20 to about 80 percent.

The ‘575 patent disclose a spiroid braided suture having one or more yarns of UHMWPE where the remainder of the yarns are non-absorbable yarns. Ex. 15 at col. 4, ll. 8-24; FIG. 6. Dr. Hermes agreed that FIG. 6 of the ‘575 patent discloses that more than one yarn (item 26) can be made of UHMWPE with and that one or more of the yarns (item 26) can be a non-absorbable yarn. Ex. 10 at 207:12-21. Since the ‘575 patent discloses that UHMWPE can make up any number of yarns of the suture, the ‘575 patent plainly includes a volume fraction of the first fiber-forming material between about 20-80%.

²³ As stated above, the asserted dependent claims all contain the limitations of claim 1 plus additional limitations. As we demonstrated above, the limitations from claim 1 (included in the dependent claims) are all disclosed by the ‘575 patent.

²⁴ Moreover, claim 12 of the ‘575 patent (Ex. 15 at col. 8, l. 62) discloses that the second fiber-forming material is polyester, a term synonymous with PET. *See supra* at n. 22.

Asserted claim 12 adds both the requirement that the second fiber forming material be PET (the additional limitation from claim 8) and that a needle be attached to the suture (the additional limitation of claim 2). For the same reasons discussed in connection with claim 2 and claim 8, claim 12 is also anticipated by the '575 patent.

For all the foregoing reasons, the asserted claims of the '446 patent are anticipated by the '575 patent.

IV. CONCLUSION

There are three independent reasons why summary judgment should be granted to defendants. There is no infringement because "PE" should not be construed to include UHMWPE. Therefore, FiberWire does not contain a yarn from the first set. The addition of coating to FiberWire leads to a finding of non-infringement because the undisputed evidence is that coating affects the basic and novel characteristics of the '446 patent. Finally, if the Court were to construe the term "PE" to include UHMWPE, the asserted claims of the '446 patent are invalid because the '575 patent discloses each limitation of those claims.

For all the foregoing reasons, summary judgment should be granted and DePuy Mitek's claims should be dismissed in their entirety.

Dated: August 11, 2006

Respectfully submitted,

By: /s/Charles W. Saber
Charles W. Saber
Stephen A. Soffen
Salvatore P. Tamburo
DICKSTEIN SHAPIRO LLP
1825 Eye Street, N.W.
Washington, D.C. 20006-5403
Telephone: (202) 420-3116
Facsimile: (202) 420-2201

Christopher Weld, Jr. (BBO # 522230)
Raymond P. Ausrotas (BBO # 640315)
TODD & WELD LLP
28 State Street, 31st Floor
Boston, MA 02109
Telephone: (617) 720-2626
Facsimile: (617) 227-5777

Counsel for Defendants
Arthrex, Inc. and Pearsalls Ltd.

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a
Massachusetts corporation,

Plaintiff,

vs.

ARTHREX, INC., a Delaware
corporation,

Defendant.

)
)
)
)
) CIVIL ACTION
) 04-12457 PBS
)
)
)
)
)
)

851 Gulf Shore Boulevard
Naples Beach Hotel & Golf Club
Naples, Florida
May 5, 2005
Thursday, 9:04 a.m.

VIDEOTAPED DEPOSITION
OF
ROBERT SLUSS

Taken before Tanya Ward English, Registered
Professional Reporter, Certified Realtime Reporter
and Notary Public in and for the State of Florida at
Large, pursuant to notice of taking deposition.

1 A Approximately.

2 Q Okay. So, in August 2001, there was
3 initially one FiberWire product, and now there's
4 about 50 FiberWire products, roughly. Right?

5 A Yes.

6 Q Did Arthrex ever develop a plan to add all
7 these additional products; basically fill out its
8 product line with FiberWire products?

9 MR. SABER: Objection, form. Assumes
10 facts not in evidence.

11 A No.

12 Q No?

13 So each FiberWire product required some
14 type of FDA approval, right?

15 A Yes, depending upon its use.

16 Q So there had to be an application to the
17 FDA for approval to use the FiberWire products
18 before they were marketed, right?

19 A Yes.

20 Q So sometime before the product was
21 marketed, there had to be a decision to develop it
22 and apply for FDA approval, right?

23 A Yes.

24 Q And so this had to happen roughly with
25 about 40 to 50 products, right?

1 A I don't know.

2 Q You don't know? Why not?

3 A I was not an employee of Arthrex when the
4 FDA process took place.

5 Q So you can't speak to what happened before
6 you were employed by Arthrex?

7 MR. SABER: Objection. Inconsistent with
8 the testimony. He's already told you he could,
9 and he has. You're now to areas beyond the
10 scope. I mean --

11 A No, I can't.

12 BY MR. BONELLA:

13 Q You can't. To your knowledge did Arthrex
14 ever develop any sort of plan or concept to -- let
15 me back up.

16 Would you agree, today, Arthrex has filled
17 out its product line with FiberWire products?

18 A Yes.

19 Q So did Arthrex ever develop a plan or
20 strategy to fill out its product line with FiberWire
21 products?

22 MR. SABER: Objection, vague.

23 A Can you restate the question, please, so I
24 can answer it better?

25 Q What don't you understand about the

EXHIBIT 2

***Revolutionizing
Orthopaedic Surgery***

FiberWire®

Braided Composite Suture



Revolutionizing Orthopaedic Surgery

FiberWire suture is constructed of a multi-stranded long chain ultra-high molecular weight polyethylene core with a polyester braided jacket that gives FiberWire superior strength, soft, feel and abrasion resistance that is unequaled in orthopaedic surgery. Suture breakage during knot tying is virtually eliminated, especially critical during arthroscopic procedures. FiberWire represents a major advancement in orthopaedic surgery.

Strength

FiberWire has greater strength than comparable size standard polyester suture. Multiple independent scientific studies document significant increases in strength to failure, stiffness, knot strength and knot slippage with much less elongation¹.

Biocompatibility

Extensive biocompatibility, animal and clinical testing prove that FiberWire demonstrates biocompatibility characteristics equivalent to standard polyester suture. Over two years of successful clinical outcomes in over one million orthopaedic procedures substantiate excellent biocompatibility. Biocompatibility, strength and testing results are available upon request².

Tie Ability and Knot Profile

Orthopaedic surgeons enthusiastically endorse FiberWire for its feel and knot tie ability. The first throw stays down, facilitating reproducible tissue repair. Sliding knots advance smoothly easing arthroscopic knot tying procedures. Superior strength allows tighter loop security during knot tying, increasing knot integrity while reducing the knot profile compared to standard polyester suture.

Abrasion Resistance

The multi-strand long chain ultra-high molecular weight polyethylene core dramatically increases FiberWire abrasion resistance. Surgical procedures that create bone edges, tunnel edges, and articulating surface abrasion areas are appropriate indications for FiberWire. FiberWire is over five times more abrasion resistant than standard polyester suture.

Variety

The FiberWire family has expanded to sizes 4-0 through #5 including new designs such as FiberStick and FiberSnare that provide innovative solutions to arthroscopic suture passing. TigerWire has a black spiral thread for easier arthroscopic visualization, identification, sizing and motion detection. FiberLoop is ideal for multistrand tendon repairs.

Safety in Numbers

Trusted by leading orthopaedic surgeons worldwide since its introduction in 2002, FiberWire has contributed to successful surgical outcomes in over one million orthopaedic surgical procedures ranging from Achilles tendon repair to rotator cuff repair. Multiple scientific publications have confirmed the advantages of FiberWire in orthopaedic surgery^{3,4}.

References on back...

FiberWire Suture Family

FiberWire

FiberWire suture is a new generation of polyester suture with a long chain polyethylene core. FiberWire has greater strength than similar sized polyester suture with superior feel, smooth tie ability and lower knot profile. FiberWire is the ideal suture for most orthopaedic soft tissue repairs, virtually eliminating suture breakage during knot tying.

#2 FiberWire, 38 inches (blue) w/Tapered Needle, 26.5 mm 1/2 circle	AR-7200
#2 FiberWire, 38 inches (blue) w/Reverse Cutting Needle, 36.6 mm 1/2 circle	AR-7202
#2 FiberWire Loop w/Needle for NeedlePunch, 26 inches (green), 10 mm, straight	AR-7204
#2 FiberWire, 38 inches (blue) w/two Tapered Needles, 26.5 mm 1/2 circle	AR-7205
#2 FiberWire, 38 inches w/Tapered Needle (blue), 36.6 mm 1/2 circle	AR-7206
#2 FiberWire w/two Needles for NeedlePunch, 38 inches (blue), 10 mm, straight	AR-7207
#2 FiberWire, 38 inches (1 blue, 1 white/black) w/Tapered Needle, 26.5 mm 1/2 circle	AR-7208
#5 FiberWire, 38 inches (blue)	AR-7210
#5 FiberWire, 38 inches (blue) w/Conventional Cutting Needle, 48 mm 1/2 circle	AR-7211
2-0 FiberWire, 18 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle	AR-7220
2-0 FiberWire, 38 inches (blue)	AR-7221
2-0 Suture Shuttle Loop for NeedlePunch, 40 mm	AR-7224
3-0 FiberWire, 18 inches (blue) w/Diamond Point Needle, 26.2 mm 3/8 circle	AR-7225
3-0 FiberWire, 18 inches (blue) w/Tapered Needle, 15 mm 3/8 circle	AR-7227-01
3-0 FiberWire, 18 inches (blue) w/Reverse Cutting Needle, 16.3 mm 3/8 circle	AR-7227-02
4-0 FiberWire, 18 inches (blue) w/Diamond Point Needle, 18.7 mm 3/8 circle	AR-7228
4-0 FiberWire, 18 inches (blue) w/Tapered Needle, 12.3 mm 3/8 circle	AR-7230-01
4-0 FiberWire, 18 inches (blue) w/Reverse Cutting Needle, 11.9 mm 3/8 circle	AR-7230-02
0 FiberWire, 38 inches (blue) w/Tapered Needle, 22.2 mm 1/2 circle	AR-7250
0 FiberWire, 38 inches (blue) w/Diamond Point Needle, 22.2 mm 1/2 circle	AR-7251

TigerWire®

TigerWire suture utilizes the same high strength construction as FiberWire except that it contains a black marker strand in the suture weave. This strand appears as a stripe in the suture making suture identification easier during joint reconstruction and soft tissue repairs.

#2 FiberWire, 38 inches (blue, white/black)	AR-7201
#2 TigerWire, 38 inches (white/black)	AR-7203
#2 TigerWire, 38 inches (white/black) w/two Tapered Needles, 26.5 mm 1/2 circle	AR-7205T

FiberStick™ and TigerStick™

The stiff "waxed" end of the FiberStick and TigerStick allows convenient and easy advancement through most cannulated instruments or spinal needles, alleviating the need for a monofilament suture or wire suture shuttle. FiberStick and TigerStick come with a thin plastic tube which protects the stiffened suture end until use.

FiberStick, #2 FiberWire, 50 inches (blue) one end stiffened, 12 inches	AR-7209
TigerStick, #2 TigerWire, 50 inches (white/black) one end stiffened, 12 inches	AR-7209T
2-0 FiberStick, 2-0 FiberWire, 50 inches (blue) one end stiffened, 12 inches	AR-7222



FiberWire Suture Family

FiberTape™

FiberTape is an ultra-high strength 2 mm width tape using a similar long chain polyethylene structure as the FiberWire suture. In addition to high demand applications like AC joint reconstruction, the broad footprint of the FiberTape is appropriate for repairs in degenerative cuff tissue where tissue pull-through may be a concern.

FiberTape, 2 mm, 54 inches (blue) each end tapered to #2 FiberWire, 8 inches

AR-7237

FiberLoop™

FiberLoop is a suture option for multi-strand tendon repairs. These small diameter looped FiberWire products, in 12 and 20 inch lengths, allow for strong multi-strand flexor and extensor tendon repairs while reducing tendon damage from multiple needle passes. FiberLoop is available with 17.9 mm tapered needles to prevent cutting suture while stitching.

4-0 FiberLoop, 4-0 FiberWire, 12 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle

AR-7229-12

4-0 FiberLoop, 4-0 FiberWire, 20 inches (blue) w/Tapered Needle, 17.9 mm 3/8 circle

AR-7229-20

2-0 FiberLoop, 30 inches w/Diamond Point Needle, 48 mm 1/2 circle

AR-7232-01

2-0 FiberLoop, 24 inches w/Diamond Point Needle, 26.2 mm 3/8 circle

AR-7232-02

2-0 FiberLoop, 30 inches w/Diamond Point Straight Needle, 64.8 mm

AR-7232-03

FiberSnare™

FiberSnare with closed loop provides an easy one step approach to creating a FiberWire loop on the tip of the Bio-Tenodesis Driver. Instead of using a nitinol wire, insert the stiff non-looped end retrograde through the tip of the Bio-Tenodesis Screwdriver. Place the tip of the tendon or tendon graft into the FiberWire loop and cinch the other end around the suture cleat on the back end of the blue Tear Drop Handle. The FiberSnare can also be used as a suture shuttle for passage of traction sutures through bone tunnels.

#2 FiberSnare, #2 FiberWire, 26 inches, (green) stiffened w/closed loop, 12 inches

AR-7209SN

2-0 FiberWire Meniscus Repair Needles

2-0 FiberWire with Meniscus Needles is an excellent option for standard outside/in meniscus repair. The swedged-on FiberWire suture enables the surgeon to efficiently slide low profile knots while creating the strongest suture repair possible. The stainless steel meniscal needles easily pass through meniscal and soft tissues.

#2-0 FiberWire Meniscus Repair Needles

AR-7223

FiberWire Suture Kit

The FiberWire Suture Kit is available for larger complex soft tissue approximation procedures. This kit contains a total of 18 sutures including three different colored versions of #5 FiberWire for easy suture differentiation, large cutting Spring Eye Free Needles, and #2 FiberWire in one convenient package.

FiberWire Suture Kit

AR-7219

Suture Anchors with FiberWire

Suture Anchors

A recent innovation that has had a significant impact on the performance of suture anchors is the availability of FiberWire suture in our suture anchors. The high strength characteristics along with significantly increased abrasion resistance gives the surgeon confidence during crucial knot tying stages where suture breakage is virtually eliminated. Each suture anchor is available with one or two strands of FiberWire and black/white striped TigerWire to facilitate suture differentiation and motion determination.

Our anchors are now available loaded with two strands of a two-toned FiberWire product, TigerTail. TigerTail, available in either blue or white, has a black stripe in one half of the suture. Anchors double loaded with TigerTail will have four visually distinct strands of FiberWire to enhance suture strand differentiation, virtually eliminating suture strand confusion.

Micro Bio-SutureTak w/Needles, 2.4 mm x 5 mm, w/handled inserter and 2-0 FiberWire
 Mini Bio-SutureTak w/Needles, 2.4 mm x 7 mm w/2-0 FiberWire
 Small Bone FASTak Suture Anchor, 2.4 mm x 7.5 mm w/2-0 FiberWire
 FASTak Suture Anchor, 2.4 mm x 11.7 mm w/and #2 FiberWire
 FASTak II Suture Anchor, 2.8 mm x 11.7 mm w/#2 FiberWire
 FASTak II Suture Anchor, 2.8 mm x 11.7 mm w/#2 FiberWire
 Bio-FASTak Suture Anchor, 3 mm x 14 mm w/two #2 FiberWire
 Bio-FASTak Suture Anchor, 3 mm x 14 mm w/two #2 FiberWire
 Corkscrew II Suture Anchor, 5 mm x 15.5 mm w/two #2 FiberWire (2 eyelets) (a)
 Corkscrew Suture Anchor, 3.5 mm x 12 mm w/#2 FiberWire
 Corkscrew Suture Anchor w/Needles, 3.5 mm x 12 mm w/two #2 FiberWire
 Bio-Corkscrew Suture Anchor, 3.7 mm x 17.9 mm w/two #2 FiberWire
 Corkscrew Suture Anchor w/Needles w/handled inserter and two #2 FiberWire, 5 mm x 15.5 mm
 Corkscrew Suture Anchor, 5 mm x 15.5 mm w/two #2 FiberWire
 Bio-Corkscrew Suture Anchor, 5 mm x 15 mm w/two #2 TigerTail (b)
 Bio-Corkscrew Suture Anchor, 3.7 mm x 17.9 mm, w/two #2 TigerTail
 Bio-Corkscrew Suture Anchor, 5 mm x 17.9 mm w/two #2 FiberWire,
 Bio-Corkscrew Suture Anchor w/Needles, 5 mm x 17.9 mm w/two #2 FiberWire
 Bio-Corkscrew Suture Anchor, 5 mm x 17.9 mm w/2 mm FiberTape
 Corkscrew Suture Anchor w/Needles, 5 mm x 15.5 mm w/two #2 FiberWire
 Corkscrew Suture Anchor, 5 mm x 15.5 mm w/two #2 TigerTail
 Bio-Corkscrew Suture Anchor w/NeedlePunch Needles, 5 mm x 17.9 mm w/two #2 FiberWire
 Bio-Corkscrew Suture Anchor, 6.5 mm x 17.9 mm w/two #2 FiberWire
 Bio-Corkscrew Suture Anchor w/Needles, 6.5 mm x 17.9 mm w/two #2 FiberWire
 Corkscrew Suture Anchor, 6.5 mm x 15.5 mm w/two #2 FiberWire
 Bio-Corkscrew FT Suture Anchor, 5.5 mm x 15 mm w/two #2 FiberWire (d)
 Bio-Corkscrew FT Suture Anchor, 5.5 mm x 15 mm, w/two #2 TigerTail
 Bio-Corkscrew FT Suture Anchor w/Needles, 5.5 mm x 15 mm w/two #2 FiberWire
 Bio-Corkscrew FT w/NeedlePunch Needles, 5.5 mm x 15 mm w/two #2 FiberWire
 Bio-Corkscrew FT w/ four NeedlePunch Needles, 5.5 mm x 15 mm w/two #2 FiberWire (for mini open procedures only)
 Corkscrew FT II Suture Anchor w/NeedlePunch Needles, 5.5 mm x 14 mm w/two #2 FiberWire
 Corkscrew FT II Suture Anchor, 5.5 mm x 16 mm w/two #2 FiberWire
 Corkscrew FT II Suture Anchor, 5.5 mm x 16 mm w/two #2 TigerTail
 Corkscrew FT II Suture Anchor w/two #2 FiberWire, 5.5 mm x 14 mm (c)
 Corkscrew FT II Suture Anchor w/Needles, w/two #2 FiberWire with 26 mm 1/2 circle needles, 5.5 mm x 14 mm
 PEEK Corkscrew FT II Suture Anchor, 5.5 mm x 14 mm w/two #2 FiberWire
 Bio-SutureTak Suture Anchor w/#2 FiberWire, 3 mm x 14 mm (e)
 Bio-SutureTak Suture Anchor w/two #2 FiberWire, 3 mm x 14 mm
 Bio-SutureTak Suture Anchor, 3 mm x 14 mm w/#2 TigerTail
 Bio-SutureTak Suture Anchor, 3.7 mm x 14 mm w/#2 FiberWire
 Bio-SutureTak Suture Anchor, 3.7 mm x 16 mm w/#2 TigerTail
 PEEK SutureTak Suture Anchor, 3 mm x 12 mm w/#2 FiberWire

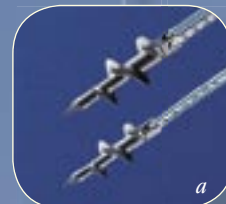
AR-1320BNF
 AR-1322BNF
 AR-1322-752SF
 AR-1322SXF
 AR-1324HF
 AR-1324SF
 AR-1324BF
 AR-1324BF-2
 AR-1902SF
 AR-1915SF
 AR-1915SNF
 AR-1920BF-37

AR-1920SNF
 AR-1920SF
 AR-1920BFT
 AR-1920BFT-37
 AR-1920BF
 AR-1920BNF
 AR-1920BT
 AR-1920NSF
 AR-1920SFT

AR-1920BNP
 AR-1925BF
 AR-1925BNF
 AR-1925SF
 AR-1927BF
 AR-1927BFT
 AR-1927BNF
 AR-1927BNP

AR-1927BNP4
 AR-1928NP-2
 AR-1928SF
 AR-1928SFT-2
 AR-1928SF-2

AR-1928SNF-2
 AR-1928PSF-2
 AR-1934BF
 AR-1934BF-2
 AR-1934BFT
 AR-1934BLF
 AR-1934BLFT
 AR-1934PS



FiberWire Accessories

Suture Cutters

The Suture Cutters were designed to facilitate arthroscopic suture cutting with specially designed cutting jaws, with and without visual control.

The Suture Cutter's precision jaws prevent knot cutting by leaving a length of reproducible suture tail, 3 mm for the 4.2 mm outer diameter cutter and 1 mm for the 2.75 mm outer diameter cutters, without direct visual control. These cutters have a special locking device to prevent premature suture cutting. The blunt tip of the cutter is excellent for knot pushing.

The Open Ended Suture Cutter was designed to speed up the suture cutting process. This cutter allows for quick and efficient suture tail cutting under direct visual control through the same or alternate cannula or portal. The notch on the side of the cutter tip automatically guides the suture tails into the front cutting slot for an accurate cut from any angle.

All Suture Cutters are recommended for cutting FiberWire.

Suture Cutter, 4.2 mm, straight
2-0 Suture Cutter, 2.75 mm, straight
2-0 Suture Cutter, 2.75 mm, 15° up curve
Suture Cutter, Open Ended, Left Notch

AR-12250
AR-11790
AR-11791
AR-11794L

FiberWire Scissor

The FiberWire Scissor was designed to cut any size or style suture, especially FiberWire, in open surgical cases where an arthroscopic suture cutter is not necessary. With its specially designed cutting edges, it can cut FiberWire cleanly and effortlessly without frayed edges. The color coded handle facilitates instrument differentiation in large instrument packs.

FiberWire Scissor
FiberWire Scissor, small

AR-11796
AR-11797

FingerShield™

The FingerShield is a woven white polyester sleeve with an embedded radiopaque blue marker designed to reduce pressure induced lacerations to the digits of the hand caused by repetitive knot tying during surgical cases. They slip right over sterile gloves when needed. The tips are left open to allow pinch grasp of suture strands while still protecting the IP joint area of each digit. The soft, finger conforming weave will stand up to repetitive hand tying during a case without constraining the fingers. Suture slides over the FingerShield smoothly and effortlessly. There are two FingerShields per sterile pack.

FingerShield, 2/pk

AR-7199

FiberWire Tensioner

The FiberWire Tensioner provides controlled tensioning of FiberWire loops during knot tying when reapproximating soft tissue. The blunt tip keeps the knot in place while the tensioning wheel and spring mechanism gently tension the loop to tighten the repair. It is appropriate for use in conjunction with #5 FiberWire.







FiberWire Tensioner
Suture Passing Wire
#5 FiberWire, 38 inches (blue)

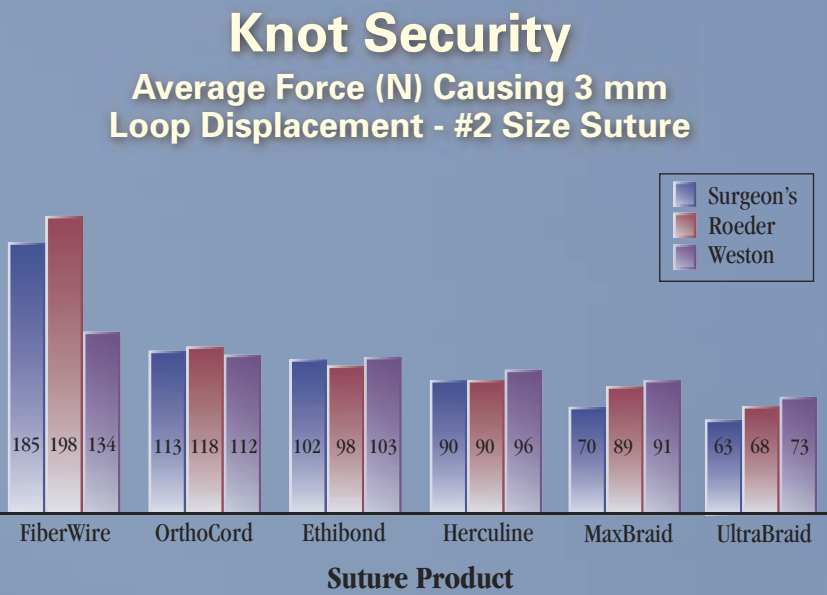
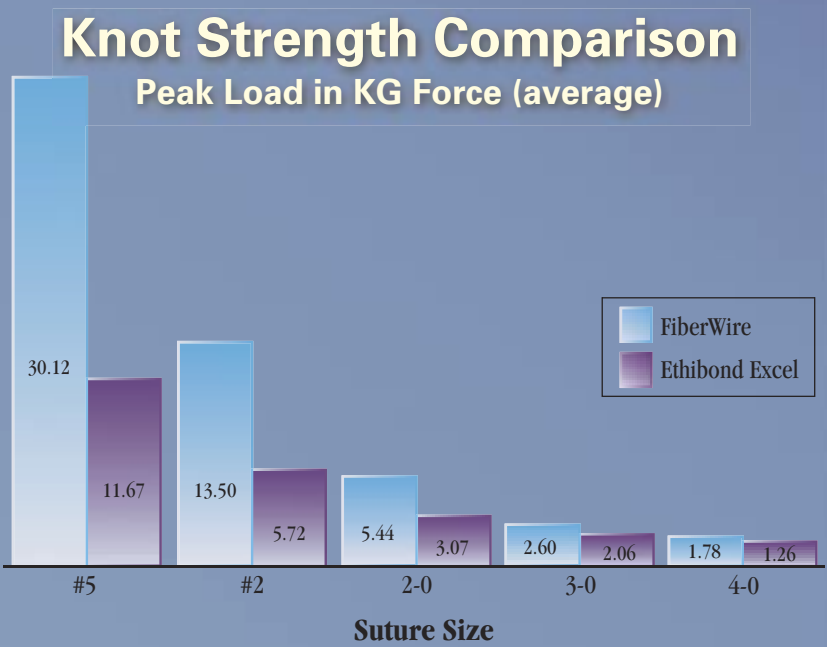
AR-1929
AR-1255-18
AR-7210



Detach and Hang

Arthrex FiberWire® Reference Chart

FiberWire									
Suture Size	Suture Length	Description	Needle Dimensions	Needle Reference	Recommended Uses	Supplied	Cat Number	Box Color	Actual Size of Needles
#5 (7 metric)	38 inches	1 strand (blue)			Use with FiberWire Tensioner for Tendon, Ligament or Soft Tissue Repair, AC Joint Repair	12/box	AR-7210		
#5 (7 metric)	38 inches	1 strand (blue) with Conventional Cutting Needle	48 mm 1/2 circle	CCS-1	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7211		
#2 (5 metric)	38 inches	1 strand (blue) with Tapered Needle	26.5 mm 1/2 circle	T-5	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7200		
#2 (5 metric)	38 inches	2 strands (blue, white/black)			Reload suture anchors, use with Viper	12/box	AR-7201		
#2 (5 metric)	38 inches	1 strand (blue) w/Reverse Cutting Needle	36.6 mm 1/2 circle	C-13	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7202		
#2 (5 metric)	38 inches	1 strand (white/black) TigerWire			Reload Suture Anchors	12/box	AR-7203		
#2 (5 metric)	26 inches	1 strand (blue) w/closed Loop and NeedlePunch Needles	10 mm		Rotator Cuff Repair	10/box	AR-7204		
#2 (5 metric)	38 inches	1 strand (blue) w/two Tapered Needles	26.5 mm 1/2 circle	T-5	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7205		
#2 (5 metric)	38 inches	1 strand (blue) w/Tapered Needle	36.6 mm 1/2 circle	T-5	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7206		
#2 (5 metric)	38 inches	1 strand (white/black) TigerWire w/two Tapered Needles	26.5 mm 1/2 circle	T-5	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7205T		
#2 (5 metric)	38 inches	1 strand (blue) w/two NeedlePunch Needles	10 mm		Rotator Cuff Repair	10/box	AR-7207		
#2 (5 metric)	38 inches	2 strands (blue, white/black) w/Tapered Needle	26.5 mm 1/2 circle	T-5	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7208		
2-0 (3 metric)	18 inches	1 strand (blue) w/Tapered Needle	17.9 mm 3/8 circle	T-13	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7220		
2-0 (3 metric)	38 inches	1 strand (blue)			Meniscal Repair	12/box	AR-7221		
3-0 (2 metric)	18 inches	1 strand (blue) w/Diamond Point Needle	26.2 mm 3/8 circle	DE-14	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7225		
3-0 (2 metric)	18 inches	1 strand (blue) w/Tapered Needle	15 mm 3/8 circle	T-43	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7227-01		
3-0 (2 metric)	18 inches	1 strand (blue) w/Reverse Cutting Needle	16.3 mm 3/8 circle	C-22	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7227-02		
4-0 (1.5 metric)	18 inches	1 strand (blue) w/Diamond Point Needle	18.7 mm 3/8 circle	DE-10	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7228		
4-0 (1.5 metric)	18 inches	1 strand (blue) w/Tapered Needle	12.3 mm 3/8 circle	T-12	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7230-01		
4-0 (1.5 metric)	18 inches	1 strand (blue) w/Reverse Cutting Needle	11.9 mm 3/8 circle	C-17	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7230-02		
0 (1.5 metric)	38 inches	1 strand (blue) w/Tapered Needle	22.2 mm 1/2 circle	T-4	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7250		
0 (1.5 metric)	38 inches	1 strand (blue) w/Diamond Point Needle	22.2 mm 1/2 circle	D-10	Tendon, Ligament or Soft Tissue Repair	12/box	AR-7251		
FiberStick									
#2 (5 metric)	50 inches	1 strand (blue) one end stiffened, 12 inches			Rotator Cuff Repair, Glenoid Labrum Repair and Capsular Plication	5/box	AR-7209		
#2 (5 metric)	50 inches	1 strand (black/white) one end stiffened, 12 inches			Rotator Cuff Repair, Glenoid Labrum Repair and Capsular Plication	5/box	AR-7209T		
2-0 (3 metric)	50 inches	1 strand (blue) one end stiffened, 12 inches			Rotator Cuff Repair, Glenoid Labrum Repair, Capsular Plication, TFCC Repair and Meniscal Repair	5/box	AR-7222		
FiberTape									
	54 inches	2 mm (blue) each end tapered to #2 FiberWire, 8 inches			AC Joint Repair	6/box	AR-7237		
FiberSnare									
#2 (5 metric)	26 inches	1 strand (green) stiffened w/closed loop, 12 inches			Use with Bio-Tenodesis Driver for Tendon Snare	12/box	AR-7209SN		
FiberLoop									
4-0 (1.5 metric)	12 inches	1 strand (blue) w/Tapered Needle	17.9 mm 3/8 circle	T-13	Multi-strand Tendon Repairs	12/box	AR-7229-12		
4-0 (1.5 metric)	20 inches	1 strand (blue) w/Tapered Needle	17.9 mm 3/8 circle	T-13	Multi-strand Tendon Repairs	12/box	AR-7229-20		
2-0 (1.5 metric)	30 inches	1 strand (blue) w/Diamond Point Needle	48 mm 1/2 circle	DE-14	Multi-strand Tendon Repairs	12/box	AR-7232-01		
2-0 (1.5 metric)	24 inches	1 strand (blue) w/Diamond Point Needle	26.2 mm 3/8 circle	D-17	Multi-strand Tendon Repairs	12/box	AR-7232-02		
2-0 (1.5 metric)	30 inches	1 strand (blue) w/Diamond Point Straight Needle	64.8 mm	SD-2	Multi-strand Tendon Repairs	12/box	AR-7232-03		
FiberWire Suture Kit									
#5 (7 metric)	38 inches	4 strands (blue), 4 strands (white) and 4 strands (green)	60 mm 3/8 circle, 80 mm 1/2 circle		Soft Tissue Fixation	1/box	AR-7219		
#2 (5 metric)	38 inches	6 strands (blue) w/Tapered needle	26.5 mm 1/2 circle	T-5	Soft Tissue Reconstruction				



* Data on file

References:

- ¹ Burkhart SS. *Arthroscopic Knots: The Optimal Balance of Loop Security and Knot Security*. Arthroscopy 2004; 20.
- ² *FiberWire™: Collective Summary of Strength and Biocompatibility Testing Data Comparisons of Polyester and Polyblend Sutures*. Study presented from in-house testing, 2001; LA0235
- ³ Lo I KY, Burkhart SS. *Biomechanical Principles of Arthroscopic Repair of the Rotator Cuff*. Operative Techniques in Orthopaedics 2002; 12-3:140-155.
- ⁴ Deakin M, Stubbs D, Goldberg J, Bruce W, Gillies RM, Walsh WR. *Effect of Suture Type, Anchor and Testing Orientation of the Static Properties of Suture Anchors*. A Poster Presentation, #1536. 50th Annual Meeting of the Orthopaedic Research Society.



Arthrex, Inc.
1370 Creekside Boulevard, Naples, Florida 34108-1945 • USA
Tel: 239-643-5553 • Fax: 239-598-5534 • Website: www.arthrex.com

Arthrex GmbH
Liebigstrasse 13, D-85757 Karlsfeld/München • Germany
Tel: +49-8131-59570 • Fax: +49-8131-5957-565

Arthrex Latin América
3750 NW 87th Avenue, Miami, Florida 33178 • USA
Tel: 954-447-6815 • Fax: 954-447-6814

Arthrex S.A.S.
5 Avenue Pierre et Marie Curie, 59260 Lezennes • France
Tel: +33-3-20-05-72-72 • Fax: +33-3-20-05-72-70

Arthrex Canada
Lasswell Medical Co., Ltd., 405 Industrial Drive, Unit 21, Milton, Ontario • Canada L9T 5B1
Tel: 905-876-4604 • Fax: 905-876-1004 • Toll-Free: 1-800-224-0302

Arthrex GesmbH
Triesterstrasse 10/1 • 2351 Wiener Neudorf • Austria
Tel: +43-2236-89-33-50-0 • Fax: +43-2236-89-33-50-10

Arthrex Bvba
Mechelsesteenweg 23, 2540 Hove • Belgium
Tel: +32-3-2169199 • Fax: +32-3-2162059

Arthrex Ltd.
Unit 16, President Buildings, Savile Street East, Sheffield S4 7UQ • England
Tel: +44-114-2767788 • Fax: +44-114-2767744

Arthrex Hellas - Medical Instruments SA
43, Argous Str. - N. Kifissia, 145 64 Athens • Greece
Tel: +30-210-8079980 • Fax: +30-210-8000379

Arthrex Sverige AB
Turbinvägen 9, 131 60 Nacka • Sweden
Tel: +46-8-556 744 40 • Fax: +46-8-556 744 41

Arthrex Korea
Rosedale Building #1904, 724 Sooseo-dong, Gangnam-gu, Seoul 135-744 • Korea
Tel: +82-2-3413-3033 • Fax: +82-2-3413-3035

U.S. PATENT NO. 5,964,783; 6,117,162; 6,214,031; 6,511,499; 6,652,563 and 6,716,234

©Copyright Arthrex Inc., 2005. All rights reserved. LB0235E



EXHIBIT 3

EXTENDED-CHAIN FIBER

SPECTRA®
EXTENDED CHAIN
POLYETHYLENE FIBERS

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI003378

SPECTRA®

**HIGH PERFORMANCE FIBERS
FOR REINFORCED COMPOSITES**

Published by
Allied Fibers Technical Center
P.O. Box 31
Petersburg, Virginia 23804
804/520-3321

© Copyright Allied Signal Inc. 1988

Spectra® 900 and Spectra® 1000 are trademarks of Allied Signal Inc.
for its series of ultra high strength fibers

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI003379

SPECTRA® EXTENDED CHAIN POLYETHYLENE FIBERS

David S. Cordova, Daniel Scott Donnelly
Allied-Signal Technologies
Fibers Division
Petersburg, VA 23804

1. HISTORY

Extended Chain Polyethylene (ECPE) fibers are the most recent entrants in the high performance fibers field. SPECTRA® ECPE, the first commercially available ECPE fiber, was introduced in February 1985. They are the first in a family of extended chain polymers manufactured by Allied-Signal Corporation.

SPECTRA® ECPE fibers are, pound for pound, the highest modulus and strongest fibers ever made. This is a noteworthy achievement on two counts. First, because industry had relegated it to the status of a general purpose commodity polymer, polyethylene was not considered as a specialized high performance product. Second, the discovery was not made in a large industrial polymer laboratory, but from fundamental work by researchers in several leading universities. Although the work was supported by industry, the immediate outcome was not foreseen as a commercial entity. It is, however, an example of industry recognizing the value of revolutionary findings and exploiting the promise of technology. The result was the transformation of a commodity type polyethylene (PE) plastic into a high performance fiber.

Today, ECPE fibers are being utilized as a reinforcement in areas that, five years ago, were not accessible to any organic fiber. Applications such as ballistic armor, impact shields, and radar domes are being developed to take advantage of the unique properties of ECPE.

2. CHEMISTRY

SPECTRA® fibers are made from ultra-high molecular weight polyethylene (UHMPE). In contrast to aramids, PE is a flexible molecule which normally crystallizes by folding back on itself. As a consequence, PE fibers made by conventional technology do not possess outstanding physical properties. ECPE fibers, on the other hand, are manufactured by a process where most of the molecules are fully extended and oriented in the fiber direction, resulting in a dramatic increase in physical properties. A simplistic view of the structure on a molecular scale could be described as a bundle of rods, with occasional entangled points that tie the structure together. Conventional PE, on the other hand, contains a number of chain folds of short length which do not make a contribution to strength.

The key structural parameters that distinguish ECPE fibers from conventional melt spun materials are further illustrated in Figure 1. The molecular weight of UHMPE is generally 1 to 5 million, whereas conventional PE fibers are typically 50,000 to several hundred thousand. SPECTRA® fibers also exhibit a very high degree of crystalline orientation (95-99%), and crystalline content (60-85%).

3. MANUFACTURING

Two general routes can be used to achieve high-modulus PE fibers. The first is by extrusion, such as melt extrusion or by solid-state extrusion, utilizing lower molecular weight PE polymer and specialized drawing techniques. These processes lead to a fiber with high modulus, but relatively low strength and high creep. The second route involves solution spinning, where very high molecular weight PE can be utilized. With this process modification, a fiber with both high modulus and high strength is produced.

The solution spinning process for a generalized extended chain fiber begins with a polymer of approximately 1-5 million molecular weight, which is dissolved in a suitable solvent. The solution serves to disentangle the polymer chains—a key step in achieving an extended chain polymer structure. The solution is fairly dilute but viscous enough to be spun using conventional melt spinning equipment. The cooling of the extrudate leads to the formation of a fiber which can be continuously dried to remove solvent or later extracted by an appropriate solvent. The fibers are generally post drawn prior to final packaging.

Unlike most high performance processes, the solution spinning process is unusually flexible, providing an almost infinite number of process and product variations. Fiber strengths from 375 KSI to 560 KSI and tensile moduli of 15 MSI to 30 MSI have been achieved on a research scale by various companies worldwide. As the solution spinning process is modified, a higher tenacity (stronger) and more thermally stable yarn is produced. Circumstantial evidence (such as increased density, heat of fusion and x-ray orientation pattern) suggests that the increased strength and stability are caused by higher degrees of molecular orientation.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS

DMI003380

4. APPLICATIONS

4.1 Fiber Properties

The comparative strengths of ECPE fibers versus other high performance fibers are summarized in Table 1. SPECTRA® 900, produced by Allied-Signal, will be used to illustrate the general properties of ECPE. SPECTRA® 1000 fibers are more stabilized, and exhibit a higher strength and modulus. In engineering terms, the tensile properties of ECPE are similar to many high performance fibers. However, because of the low density of PE (approximately 2/3 that of high modulus aramid and half that of high modulus carbon fiber), SPECTRA® fibers have extraordinarily high specific strengths and specific moduli. Pound for pound, the strength of SPECTRA® fiber is at least 35% greater than high modulus aramid or S-Glass, and about twice that of conventional high modulus carbon fiber. When comparing high performance fibers, it is often informative to employ a graphical illustration of Table 1. A two-dimensional plot of specific strength versus specific modulus for currently available fibers is given in Figure 2, again emphasizing the superior properties of SPECTRA®.

Polyethylene is also known as a system where traditional binders and wetting agents have proven to be ineffective in improving adhesion levels. ECPE fibers have shown that this characteristic is actually advantageous in specific areas. For instance, ballistic performance is inversely related to the degree of adhesion between the fiber and the resin matrix. For applications which need higher levels of adhesion and wetout, extensive research has been performed on SPECTRA® fibers. It has been found that by submitting the fiber to specific surface treatments, such as corona discharge or plasma treatments, the adhesion of the fiber to various resins is dramatically increased (see Table 2).

The main application areas being explored and commercialized today for SPECTRA® fibers are divided into two main thrusts: traditional fiber applications such as sailcloth, marine ropes, cables, sewing thread, nettings, and protective clothing; and high tech composite applications, such as ballistics, impact shields, medical implants, radomes, pressure vessels, boat hulls, sports equipment, and concrete reinforcement.

4.2 Sailcloth

World class competition of high performance sail boats (such as the Americas Cup) has become more competitive, forcing the sail industry to experiment with new materials. A winning sailcloth must possess high strength, high modulus, light weight and minimal distortion during the sailing season. Of the fiber physical properties, none are more critical than low creep and resistance to sea water and cleaning agents. Because of its superior strength-to-weight ratio and low creep response, SPECTRA® 1000 fibers are ideally suited for high performance yachting sails. Further, PE fibers are resistant to sea water and to typical cleaning solutions used in the boating industry, such as clorox (see Figure 3).

The creep behavior of SPECTRA® extended-chain fibers under typical laboratory test loadings of 3-4 gram/denier is illustrated in Figure 4. These creep levels are substantially below those encountered with conventional PE or the specialized high modulus fibers from melt spinning. At this loading, which includes the initial elastic loading component, the creep level of SPECTRA® 1000 is comparable to that of a high modulus aramid. The elastic load component is included in these results on a practical basis since it is an integral part of the sail cloth design.

4.3 Marine Ropes

High strength, light weight, low moisture absorption and excellent abrasion resistance all make ECPE a natural candidate for marine rope. Three parameters of SPECTRA® 900 rope (diameter, weight per length, and strength) are illustrated in Table 3. Since aramid fibers are the accepted standard in the high performance rope industry, aramids will be used here to provide a yardstick by which the ECPE fibers can be measured. SPECTRA® 900 braid is 12% smaller, 10% stronger and 52% lighter than the aramid product.

The important considerations in marine rope applications are load, cycling and abrasion resistance. The response of a SPECTRA® 900 rope to load cycling was measured by testing on a sheave device. The rope was repeatedly loaded to 4000 lb until it broke. In this type of test, a 12 strand ECPE braid withstood approximately eight times the number of cycles that led to failure in the control 12 strand aramid braid (Table 4). Abrasion resistance was measured by cycling the rope over an oscillating bar. In this test, 0.5 inch diameter ECPE braided rope withstood eight times the abuse of a similar aramid rope (Table 4).

4.4 Cut Resistant Gloves And Protective Clothing

The specially toughened and dimensionally stabilized SPECTRA® 1000 yarn has made a revolutionary new line of cut-resistant products. This technology offers a previously unattainable level of protection from cut and abrasion without sacrificing comfort and launderability. Spectra® fibers are being used in the form of cut resistant gloves, arm guards and chaps. Specific industries involved include: meat packing, commercial fishing, poultry processing, sheet metal work, glass cutting, and power tool use. The inert chemical nature combines with cut protection for non-permeable over-gloves in surgical, dental, laboratory testing, and police emergency response applications.

4.5 Ballistic Protection

ECPE's high strength and modulus and low specific gravity offer higher ballistic protection at a lower areal density than is possible with currently used materials. It can be used in flexible and rigid armor.

Flexible armor is manufactured by joining multiple layers of fabric into the desired shape. The style of the fabric and number of layers will determine the

ballistic resistance that the armor will provide. Typical V50 ballistic limits of plain weave SPECTRA® fabrics of different denier yarns are plotted as functions of areal density in Figure 5. Applications include protective vests for military personnel and civilian security forces as well as ballistic blankets. These blankets can be applied to ceramic and metallic armor as a front spall shield and as a rear spall suppressor. They can also be used to fabricate ballistic protective shelters.

Traditional rigid armor can also be made by utilizing woven ECPE fiber in either thermoset or thermoplastic matrices. These rigid systems exhibit high ballistic protection due to the fiber strength and modulus in combination with its low specific gravity; that is, maximum ballistic protection is achieved with minimum weight. This increased protection is illustrated in Figure 6, which compares V50 values for SPECTRA® fiber and aramid composites against a 22 caliber fragment simulator.

The ECPE fiber ballistic systems can be contoured or formed into armored plates, helicopter seats, Army or police helmets, and many other product forms. It is important for these systems to maintain their ballistic protection under a wide range of environmental conditions. For example, Figure 7 illustrates the superior performance of SPECTRA® fiber armor, even at temperatures as high as 225°F. This performance, along with the low moisture absorption, chemical inertness, and low weight characteristics make ECPE fibers a natural in the ballistic area.

4.6 Composites

ECPE fibers are recent entrants into the high performance composite industry. Their high strength and high modulus were the main attributes which attracted the composite industry, leading to the investigation of potential applications.

SPECTRA® fibers have been used with a wide variety of resin systems, including: epoxies, polyesters, vinyl esters, silicones, urethanes and polyethylene. The choice of resin is most often dictated by the end use application and requirements. Epoxy and IPN resins provide the highest mechanical properties currently reported; epoxies being used most often by the composites industry, and IPNs gaining importance in RIM/RTM processes. Vinyl ester and urethanes, on the other hand, offer the greatest impact and ballistic properties at the expense of mechanical strength. Polyester is intermediate to the two groups, and is most often used in the radome industry for its electrical properties. ECPE fibers can be processed essentially the same as aramid, graphite, and glass. Hand layup, matched mold, pressure, and vacuum molding of fabric prepreps are most often used; however, filament winding and pultrusion are also common with continuous filament.

SPECTRA® fibers can be found in various forms; roving, fabric, continuous mat, and even chopped fiber. Composite applications where high strength (i.e. tensile, flexural, or short beam shear) are needed require special fiber treatments to enhance the fiber

to matrix adhesion. Allied-Signal, Inc. has developed proprietary treatments for their SPECTRA® fibers to increase the adhesion level and composite properties.

4.6.1 Composite Applications

SPECTRA® fiber reinforced materials are being developed and used widely in ballistics, radar protective domes, aerospace, sport equipment, and industrial applications. Some of these areas utilize the fiber in hybrid form, i.e. in combination with S-2 Glass, Graphite, Aramid, and/or Quartz.

Ballistics are so far the dominant market segment. Components include helmets, helicopter seats, automotive and aircraft armor, bullet proof radomes, and other industrial structures.

Radar protective domes (radomes) is another market utilizing ECPE fibers. Because of the excellent electrical properties of polyethylene, SPECTRA® composite systems act as a shield that is virtually transparent to microwave signals, even in high frequency regions. Hybridization with quartz or glass fiber are also attractive from the structural, cost, and performance point of view.

The major sport equipment applications to date have been canoes, kayaks, snow and water skis. Numerous other sport applications are under development, including: bicycles, golf clubs, ski poles, and tennis rackets. Further growth is expected in formula race car bodies.

The industrial market is taking advantage of SPECTRA® fibers in areas where increased strength, impact resistance, non-catastrophic failure, lightweight, or corrosion resistance are required. The corrosion resistance has led the composite industry to investigate applications where parts are exposed to a wide variety of chemical elements. Until now, standard high performance fibers could not function under such adverse conditions.

5. PROPERTIES OF COMPOSITES

The various fiber characteristics discussed so far can be translated into several unique composite properties. The following discussion will be organized into the following categories:

1. Ballistic
2. Impact
3. Electrical
4. Structural

5.1 Ballistic Performance

The ballistic performance of SPECTRA® fabrics has been presented as a function of areal density and fiber denier in the ballistic protection section. The excellent protection of SPECTRA® fabrics can be translated into hard armor composites. For example, ballistic protection against .22, .30, and .50 caliber threats is summarized in Figure 8. Looking back to Figure 6, one can see the advantage of SPECTRA® composites over similar composites reinforced with aramid fibers for fragmentation protection.

Handgun projectiles present a different type of threat, and again, SPECTRA® composites face up to the challenge with reduced weight and increased protection over aramid composites. The resistance to handgun ammunition of SPECTRA® and aramid composites are compared in Table 5. In every case, the SPECTRA® composites demonstrate lower areal density and/or increased protection.

5.2 Impact Resistance

Energy dissipation is one of the most outstanding features of ECPE. For instance, a comparison of fabric composites of SPECTRA®, Glass, Kevlar and Graphite under impact conditions is presented in Table 6. The SPECTRA® composite panels had significantly better impact properties, and were not "through penetrated" as the other panels were. Another unique behavior of SPECTRA® composites under impact loading is highlighted by repetitive impact studies. Figure 9 presents repetitive impact data for a similar SPECTRA® composite panel. Toughness gradually increases after each successive impact, working to extend the actual part life.

Drop weight instrumented impact tests were also performed on honeycomb sandwich composites. Again, the peak forces resisted by the SPECTRA® plates were consistently higher than similar aramid plates (Table 7). The peak impact force, total impact energy, and energy absorbed to peak force increase with the increase in face sheet thickness, from 1 to 3 plies. Resistance to hailstorm erosion is a practical example of the advantages that can be gained from the tremendous impact resistance offered by SPECTRA® honeycomb sandwich composites. A comparison with other reinforcements in a simulated hailstorm test is shown in Figure 10.

With the new surface treatments developed to enhance the fiber-resin interface adhesion, direct effects on the impact performance can be seen in Table 6. It should be noted that although the impact properties have decreased, the impact resistance of treated SPECTRA® composites is still five times that of glass or aramid, with a significant increase in physical properties.

5.3 Electrical Properties

Radar protective covers (radomes) are gaining an increasingly important role in today's radar systems. The most important attribute for a radome to possess is to be as close to "invisible" or "transparent" to the signal as possible. Because of the low dielectric constant and loss tangent of polyethylene, (see Table 8) SPECTRA® fiber composite systems can fulfill this requirement better than any other high performance fiber. The SPECTRA® composite low dielectric constant (2.3-2.5) has been shown to hold in the high frequency ranges, even up to the millimetric band. The superior electrical properties of ECPE fibers can be utilized in single fiber systems, or can be used to improve the properties of glass radomes via hybridization. A dielectric constant of 2.9 has been obtained with a SPECTRA®/Glass (25/75) hybrid system.

The advantages of low dielectric and low loss UHSPE fibers in radar systems can be demonstrated by observing the effect of the radome on the transmission ratio. The transmitted signal of a typical SPECTRA® radome matrix is compared with a glass radome at various ratios of wall thickness to wavelength in Figure 11. The SPECTRA® radome causes much less distortion of the signal. This advantage is even more pronounced in Type A honeycomb sandwich panels (Figure 12). By causing less signal reflection and absorbance, SPECTRA® fiber composite systems are uniquely suited to radome applications.

Other possible electrical applications for ECPE fibers and their reinforced composites are electrical shelters, x-ray tables, optical cables, and other structures where high strength non-conductive characteristics are needed.

5.4 Structural Properties

Static test results for SPECTRA® 900 and SPECTRA® 1000 unidirectional composites are summarized in Table 9. All test samples were cut from unidirectional prepregs of corona treated ECPE fiber with Shell Epon 825 epoxy resin and Mellamine 5260 cycloaliphatic diamine curing agent. The strength and modulus of SPECTRA® 1000 are higher than the SPECTRA® 900 composites, due to the improved strength of the SPECTRA® 1000 fiber. Further improvements in composite properties can be achieved by applying the plasma surface treatment to the fibers. This treatment increases the interfacial bonding, which translates into even higher composite structural properties, as described previously in Table 2.

The continuing research in improving the ECPE fiber-matrix compatibility along with hybridization with other high performance fibers open a wide new area in composite properties. These developments are currently being explored by scientists at Allied-Signal.

Figure 1. Fiber Morphology.

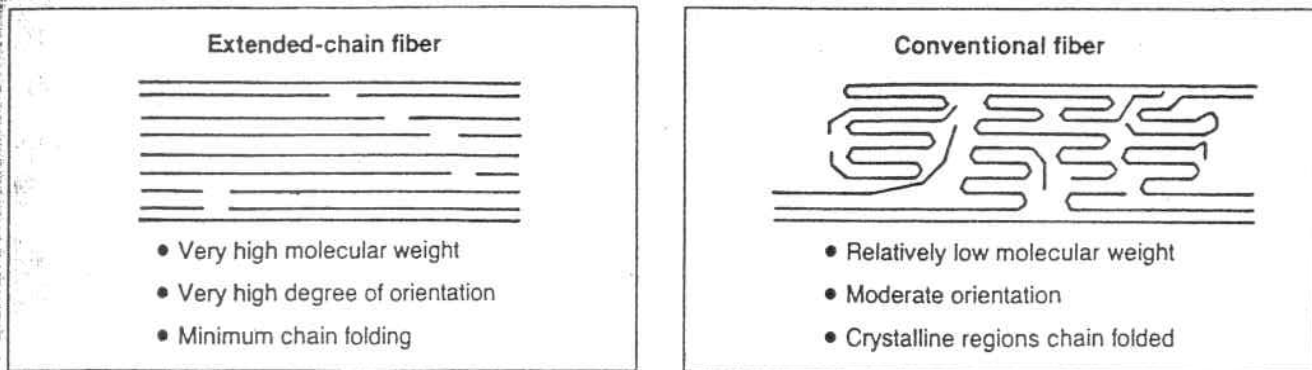


TABLE 1
HIGH PERFORMANCE FIBER PROPERTIES

	UHSPE SPECTRA 1000	ARAMID HM	ARAMID UHM*	S-Glass	Graphite HM
Property					
Density	0.97	1.44	1.47	2.49	1.86
Elongation, %	2.7	2.5	1.5	5.4	0.6
Tensile Strength, 10 ³ psi	435	400	500	665	375
Specific Strength, 10 ⁶ in	12.4	7.8	9.5	7.4	5.4
Tensile Modulus, 10 ⁶ psi	25	19	25	13	57
Specific Modulus, 10 ⁶ in	714	365	480	140	850

* Kevlar 149—Epoxy Impregnated Strand

Figure 2. Comparative tensile properties of various reinforcing fibers.

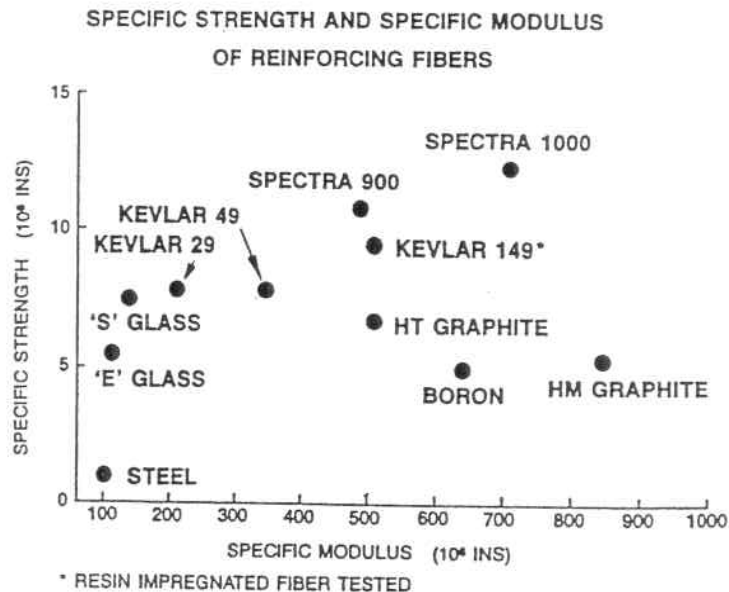


TABLE 2
UHSPE FIBER ADHESION IMPROVEMENTS

Fiber: SPECTRA® 900

Resin: Epoxy

Fiber Loading: 60%

Date	Treatment	Unidirectional			Fabric (Style 903)		
		SBS (KSI)	Flex Str (KSI)	Flex Mod (MSI)	SBS (KSI)	Flex Str (KSI)	Flex Mod (MSI)
10/85*	TN ¹	1.16	21.2	1.2	0.87	5.7	0.44
10/86	CT ²	2.61	27.6	2.6	1.4	10.3	1.0
10/87	TP ³	4.50	33.9	4.5	2.2	21.0	2.9

* Market Introduction

¹ No Treatment

² Corona Treatment

³ Plasma Treatment

Figure 3. Chemical resistance.

Agent	% Strength Retention After 6 Months Immersion	
	SPECTRA 900	Aramid
Sea Water	100	100
10% Detergent solution	100	100
Hydraulic fluid	100	100
Kerosene	100	100
Gasoline	100	93
Toluene	100	72
Perchlorethylene	100	75
Glacial acetic acid	100	82
1M Hydrochloric acid	100	40
5M Sodium hydroxide	100	42
Ammonium hydroxide (29%)	100	70
Hypophosphite solution (10%)	100	79
Clorox®	91	0

Immersed in various chemical substances for a period of 6 months, SPECTRA fibers retained their original strength.

Figure 4. Creep at 10% load (room temperature).

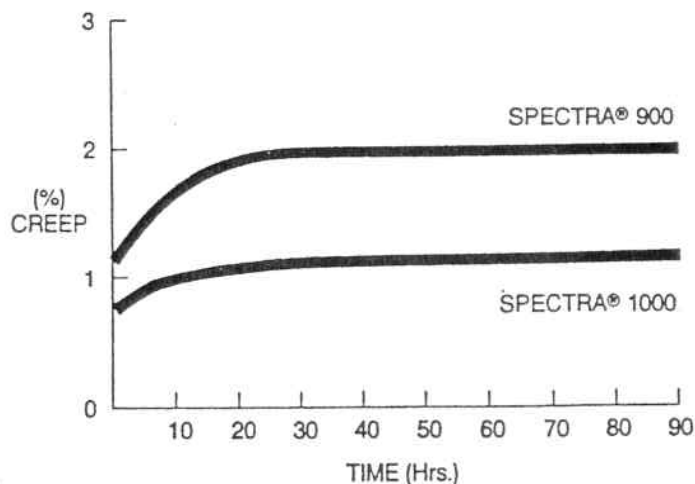


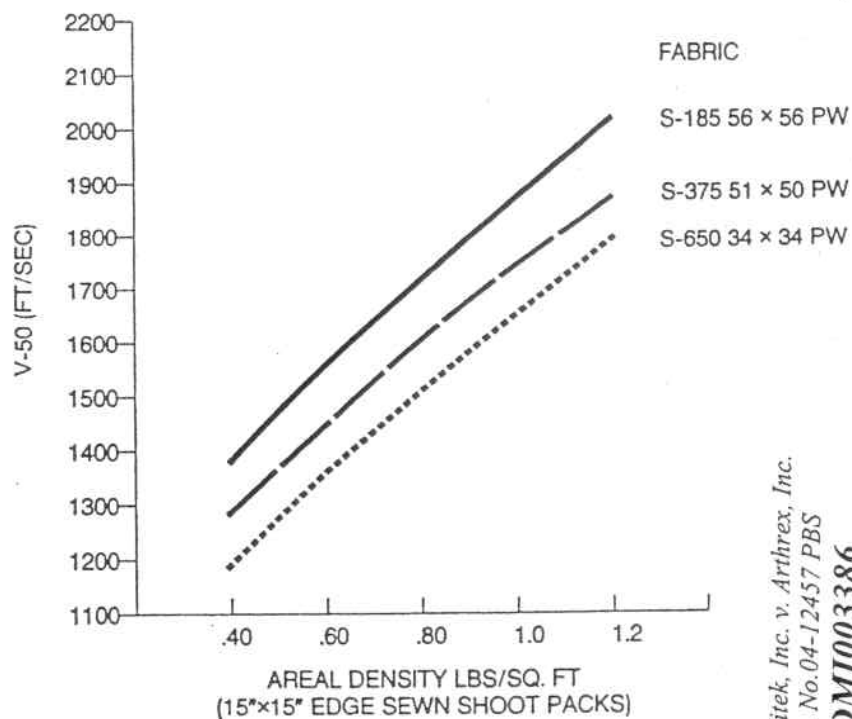
TABLE 3
COMPARATIVE PROPERTIES OF 16-STRAND ROPE

Property	SPECTRA® 900	Aramid
Diameter (In)	0.088	0.10
Wt/100 Ft (Lb)	0.153	0.32
Tensile Strength (Lb)	1465	1334

TABLE 4
CYCLE LOADING AND WEAR TESTS

	SPECTRA® 900	Aramid
Cyclic Sheave - 12 Strand Braid (10 Cycles/Min, 4000 Lb Tensile Load) Cycles to Break	10,231	1212
Oscillating Bar - 0.5 In. Rope (1.5 Cycles/Min, 1700 Lb Tensile Load) Cycles to Break	883	111

Figure 5. Ballistic performance of SPECTRA® fabrics.



.22 CAL 17 GR FSP

Figure 6. Ballistic performance of Spectra® and Aramid composites.

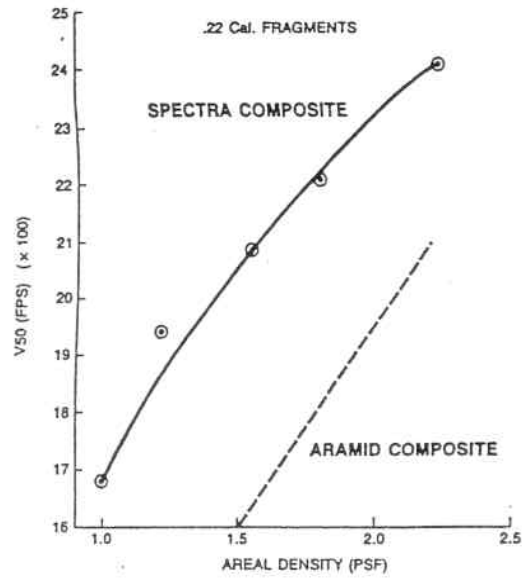


Figure 7. Spectra® fabric ballistic performance at elevated temperatures.

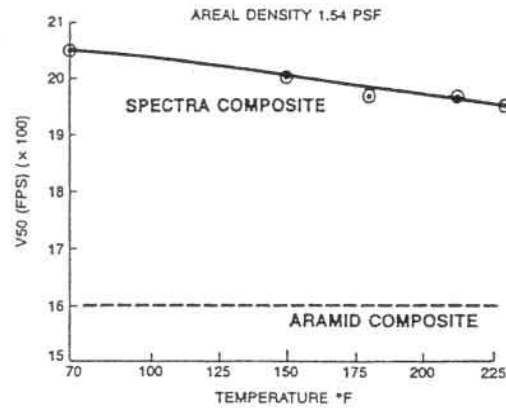


Figure 8. Spectra® composite ballistic protection versus .22, .30 & .50 caliber fragments.

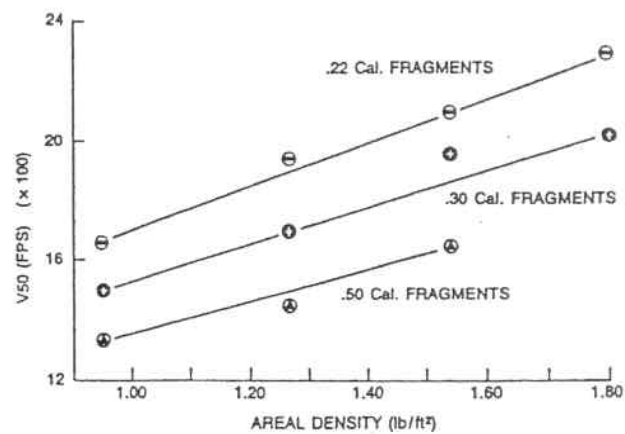


TABLE 5
RESISTANCE TO HANDGUN AMMUNITION OF
SPECTRA® AND ARAMID COMPOSITES

Ammunition	No.	Armor System	AD (PSF)	V50 (FPS)
.357 Cal. 158 grain JSP	1	Spectra/Vinylester 411-45	0.62	1220
	2	Spectra/Vinylester 411-45	1.12	1443
	3	Kevlar/Polyester	1.15	1281
	4	Spectra/Vinylester 411-45	1.36	1481
	5	Kevlar/Polyester	1.49	1311
9mm 124 grain FMJ	6	Spectra/Vinylester 411-45	0.62	1082
	7	Spectra/Latex	0.70	1200
	8	Spectra/Vinylester 411-45	0.83	1173
	9	Spectra/Latex	1.01	1454
	10	Spectra/Latex	1.23	1594
	11	Kevlar/Polyester	1.28	1241
	12	Kevlar/Polyester	1.46	1372
	13	Spectra/Latex	1.53	1624

Products: Spectra 1000 and Kevlar 29

TABLE 6
INSTRUMENTED IMPACT OF FABRIC COMPOSITES

Resin: Epoxy Resin

Fiber Vol. Loading: 60%

Fiber	Treatment	Max Load (Lb)	Energy At Max Load (Ft-Lb)	Total Energy (Ft-Lb)	Observation
SPECTRA 900	TN ¹	1660	47.4	54.5	No Penetration
SPECTRA 900	TP ²	1030	12.0	28.0	Penetration
Kevlar 49	EC ³	254	1.3	6.7	Penetration
S-2 Glass	EC	370	1.8	4.4	Penetration
HM Graphite	EC	133	1.2	2.5	Penetration

¹ No Treatment

² Plasma Treatment

³ Epoxy Compatible

Figure 9. Repetitive impact of Spectra® composites.

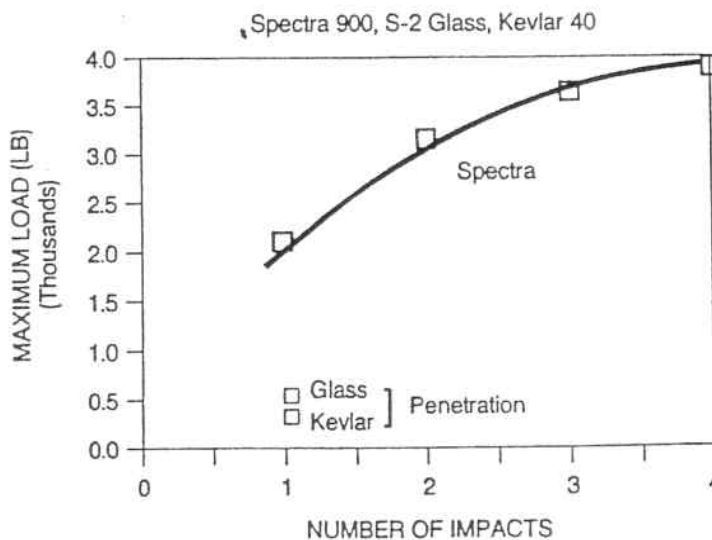


TABLE 7
IMPACT ABSORPTION OF SANDWICH COMPOSITES

Core: ½ in. honeycomb (3 lb./cu. ft.)
Resin: Epoxy (Epon 826)

Skin	No. of Layers	Energy to Peak Force (ft. lb.)	Total Energy Absorbed (ft. lb.)
SPECTRA 900	1	22.4	61.5
Aramid	1	0.7	2.3
SPECTRA 900	3	33.5	59.8
Aramid	3	1.5	10.5

Figure 10. Hailstorm test on Type A composite sandwich panels courtesy of Norton Company, Ravenna, OH.

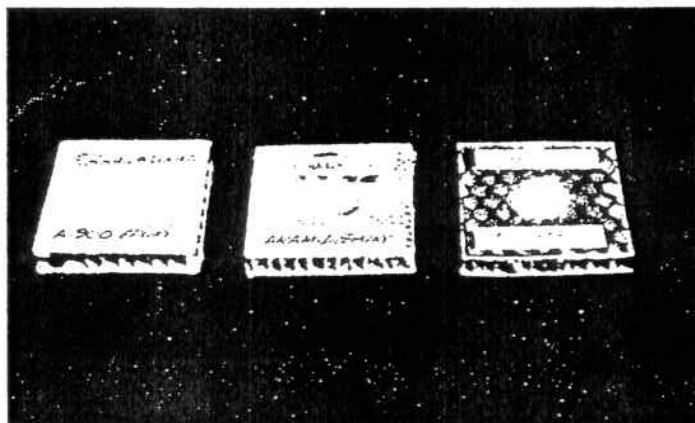


TABLE 8
FIBER ELECTRICAL PROPERTIES

Material	Dielectric Constant	Loss Tangent
SPECTRA	2.0-2.3	0.0002-0.0004
E-Glass	4.5-6.0	0.0060
Aramid	3.85	0.0100
Quartz	3.78	0.0001-0.0002

Figure 11. Transmission versus relative thickness for flat panels at 8.5 GHZ.

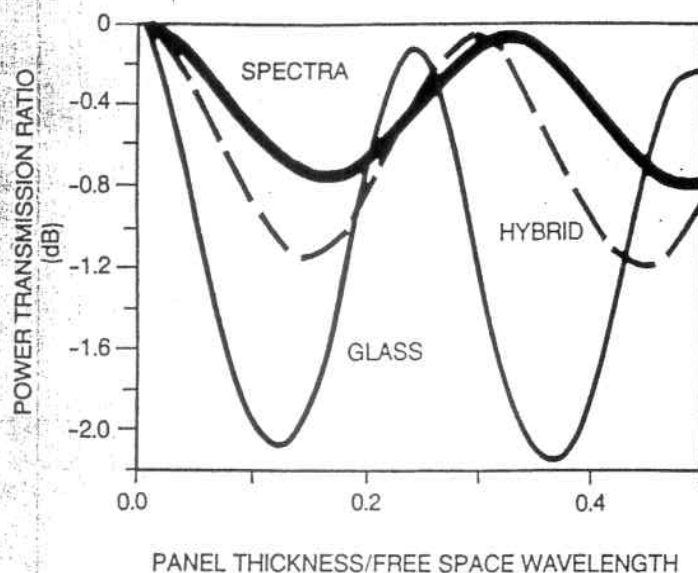


Figure 12. Transmission versus relative thickness Type A, sandwich radome test panel at 8.5 GHZ.

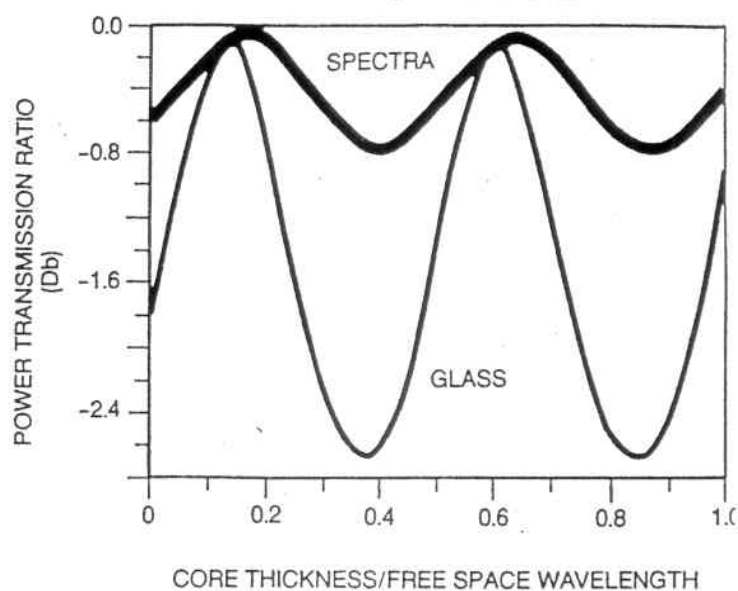


TABLE 9
PROPERTIES OF UNIDIRECTIONAL COMPOSITES
(NON TREATED FIBER)

	Spectra® 900	Spectra® 1000
Axial tensile strength (10^3 psi)	174	217
Axial tensile modulus (10^6 psi)	5.8	9.1
Axial strain to failure (%)	3.8	2.6
Major Poisson's Ratio	0.32	0.28
Transverse tensile strength (10^3 psi)	1.4	1.5
Transverse tensile modulus (10^6 psi)	0.6	0.2
Axial compressive strength (10^3 psi)	15.8	16.0
Axial compressive modulus (10^6 psi)	—	3.6
Short beam shear strength (10^3 psi)	4.0	2.5

EXHIBIT 4

Confidential Deposition of:
Shelby Cook Kornbluth

November 15, 2005

Page 1

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3 C.A. No. 04-12457 PBS

4 * * * * *

ORIGINAL

5 DePUY MITEK, INC.,

6 Plaintiff

7 v.

8 ARTHREX, INC., a Delaware

9 corporation,

10 Defendant

11 * * * * *

12 VOLUME I

13 PAGES 1-245

14
15 DEPOSITION OF DePUY MITEK, INC. by

16 SHELBY COOK KORNBLUTH, a witness called on

17 behalf of the Defendant, pursuant to the

18 Federal Rules of Civil Procedure, before

19 Jessica L. Williamson, Registered Merit

20 Reporter, Certified Realtime Reporter and

21 Notary Public in and for the Commonwealth of

22 Massachusetts, at the Hilton Hotel, 25

23 Allied Drive, Dedham, Massachusetts, on

24 Tuesday, November 15, 2005, commencing at

25 9:01 a.m.

1 A. -- I can't remember. Lupine has Panacryl.

2 I can't remember the others. I think

3 Spiralok -- I can't say.

4 **Q. What is Ethibond?**

5 A. Polyester suture.

6 **Q. And all polyester?**

7 A. Yes.

8 **Q. Does it have a coating?**

9 A. Yes.

10 **Q. And do you know what coating it has?**

11 A. Polybutylate.

12 **Q. And who makes it?**

13 A. Ethicon.

14 **Q. All right. And what is Panacryl?**

15 A. Panacryl is a copolymer of glycolide. It's

16 PGA and PLA, so polyglycolic acid and

17 polylactic acid.

18 **Q. Are either one of those a polyester?**

19 A. I can't remember. I'll have to look at the

20 chemical composition.

21 **Q. Why is Panacryl used for some of the**
22 **products?**

23 A. Because it's an absorbable suture.

24 **Q. And Ethibond is not?**

25 A. Correct.

1 Q. Ethibond is not considered a high-strength
2 suture?

3 A. No.

4 Q. Panacryl's not considered a high-strength
5 suture?

6 A. No.

7 Q. Okay. Who was the first company to sell a
8 high-strength suture?

9 MR. FALKE: Objection, outside the
10 scope of the notice. You can answer if you
11 know.

12 A. I believe it was Arthrex.

13 Q. And that was the Fiberwire product?

14 A. Yes.

15 Q. Isn't it correct that DePuy Mitek wanted to
16 develop a high-strength suture to compete
17 with Fiberwire?

18 MR. FALKE: Objection, outside the
19 scope of the notice.

20 A. Yes.

21 Q. Is it also true that DePuy Mitek considered
22 that they were losing their competitive edge
23 in the marketplace if they did not develop a
24 high-strength suture?

25 MR. FALKE: Objection, outside the

1 Q. And which one did you choose?

2 A. The copolymer of caprolactone and glycolide.

3 Q. And is that called NVC?

4 A. Yes.

5 Q. Did Ethicon in making these recommendations
6 describe to you the differences between
7 those two coatings?

8 A. I don't recall.

9 Q. Did you have any discussions with Ethicon as
10 to why there would be a coating?

11 A. No.

12 Q. Well, why is there a coating on -- there is
13 a coating on the Orthocord?

14 A. Yes.

15 Q. Why is there a coating on the product?

16 A. To help with knot sliding.

17 Q. What do you mean when you say "To help with
18 knot sliding"?

19 A. To help the knot slide down into the joint
20 so that it cinches tightly. It -- you want
21 the knot to travel down the suture.

22 Q. Okay.

23 A. And it helps with that traveling down the
24 suture.

25 Q. What do you mean when you say "it helps with

EXHIBIT 5

I will start with a quick reminder on how this project was initiated. Mitek came to us for help in the beginning of 2002. Arthrex just launched Fiberwire that began effecting Mitek's anchors business. They could not achieve their business plan objective of 17% growth per year without a high strength suture.

Ethicon initial commitment was to help with the concept feasibility phase. In the meantime, Mitek was planning to find a braiding company outside of J&J to complete development and to produce the suture. However, Mitek could not locate an outside supplier and Ethicon agreed to help in doing development and suture manufacturing.

The agreement was to develop a "me too" suture, it looked to everyone as a straightforward project. Just find raw material suppliers (UHMWPE and Polyester), use polybutylate coating and "piggyback" on the Ethibond processing conditions.

REDACTED DUE TO
ATTORNEY-CLIENT OR WORK
PRODUCT PRIVILEGE

Terry Lawler and I proposed to use an absorbable yarn instead of polyester. 60 den multifilament PDS was considered as the most suitable material—the in vivo BSR and mass absorption profile of PDS indicate that this material will maintain suture integrity for a period of 6-8 weeks. Violet PDS material is being produced by Ethicon Germany for making PDS tapes and cords, and natural PDS is used in Ethisorb production.

As I said before, the assumption was that this is an easy project that can be done in a less than a year under a relatively low budget. This project turned out more difficult than we expected. We had quite a few technical challenges that impacted project timeline and the product design.

We changed non-absorbable coating to an absorbable. We had to increase braid pick count to meet high requirements for knot security. Initial design met average requirements, but could not meet the individual requirements.

The individual requirement was not specified in the initial DIF and CPC had no test for such strong suture. This test had to be developed, and individual value was established based not only on clinical requirements, but also on competitive product assessment.

REDACTED DUE TO
ATTORNEY-CLIENT OR WORK
PRODUCT PRIVILEGE

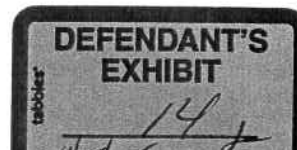
Then, PDS natural yarn was replaced with the PDS Blue yarn (dyed with D&C blue #6). That added a good additional chunk of work to the project. I will give more details when we review Blue suture development.

This slide describes the suture construction. It worth to notice that we used PDS material in the core of the suture to reduce mass of the non-absorbable material and to improve suture cutting ability during surgery.

DePuy Mitek, Inc v. Arthrex, Inc
C.A. No04-12457 PBS

DMI039558

CONFIDENTIAL
NON-PATENT
PROSECUTION COUNSEL ONLY



Because this suture is semi absorbable, it makes really difficult in assessing in vitro or in vivo performance in a conventional way. We used knot security instead of a straight tensile test. This test was done at Mitek. Each suture loop was preloaded at 2 lbs force. Mitek used a specially built fixture for each suture loop. All loops were placed in the in vitro bath for over 18 weeks. Healing period is from 6 to 8 weeks. You can see that the suture is secure up to 12 weeks. By the way, this study was done with the lower pick count suture; therefore, current suture with the higher pick count has an additional safety factor for knot security. In addition, it worth mentioning that when healing period is complete, tissue in growth takes place.

The in vivo requirement for Orthocord was established on using Ethibond straight tensile strength. At 12 weeks in vivo, the min BSR was set at 30 lbs. This suture met the requirement.

At the time, only Violet and Natural 60 denier PDS were available and we decided in addition to Violet, to develop Natural color suture for color differentiation. Initial VOC indicated that we are on the right track in. However, cadaver lab trials that simulated actual arthroscopic surgery showed poor differentiation under the arthroscopic light. We had to regroup again and find a new technical solution. After making many samples and testing them under arthroscopic light, we came to the conclusion that blue PDS gives the best differentiation from the Violet suture.

Also, this material is approved by FDA for use with the PDS yarn and was used for making fine size PDS monofilament suture.

Since use of blue PDS requires additional development work and an additional 510 k submission, the team decided to spit this project into two parts- violet and blue, so we could launch violet on schedule.

We developed a product that could be differentiated on the market. It benefits patient and a doctor. Since we used PDS material that is not available to the competitors, it would be difficult to copy this product. Also, we filed two patent applications that are going to help in additional market protection of Orthocord.

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc v. Arthrex, Inc
C.A. No04-12457 PBS
DMI039559

EXHIBIT 6

ORTHOCORD Update

15 July 2004

Ethicon, Inc.
Confidential

CONFIDENTIAL •
NON-PATENT
PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc v. Arthrex, Inc
C.A. No04-12457 PBS
DMI038133

Launch Plans

- Will initially be sold by MITEK sales force
- Original launch date: July 2004
- Delays due to:
 - Design validation issues (needle pull-off)
 - Contract issue w/ DSM (PE supplier)
- PRA on 7/15 for non-needed codes
- Re-validate needed product – will be launched late Q3 2004

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

Ethicon, Inc.
Confidential

DePuy Mitek, Inc v. Arthrex, Inc
C.A. No04-12457 PBS
DMI038137

EXHIBIT 7

ASSIGNMENT

WHEREAS, Ethicon, Inc., hereinafter referred to as the ASSIGNOR, a Corporation of New Jersey, having its principal place of business at Route 22, Somerville, New Jersey, 08876 is the owner of certain inventions or improvements for which application for Letter Patent have been made and for which Letter Patent have been issued on May 24, 1994, as U.S. Patent No. 5,314,446 entitled "Sterilized Heterogeneous Braids" (hereafter Patent Property); and

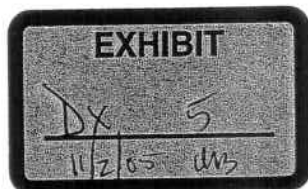
WHEREAS, DePuy Mitek, Inc., hereinafter referred to as the ASSIGNEE, a Corporation of Massachusetts, having its principal place of business at 249 Vanderbilt Avenue, Norwood, Massachusetts, 02062, is desirous of acquiring the entire right, title and interest in and to the said Patent Property in any and all countries;

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, and intending to be legally bound hereby, ASSIGNOR has sold, assigned, transferred and set over, and by these presents does hereby sell, assign, transfer and set over to said ASSIGNEE, the entire right, title and interest in and to said Patent Property and any and all continuations, divisions and renewals of and substitutes for said Patent Property and to and under any and all additional Letters Patent which may be granted on or as a result thereof in the United States and any and all other countries, and any reissue or reissues or extension or extensions of said Letters Patent, and the full right to sue for and recover damages recoverable for past infringement of the same, and for violations of provisional rights having arisen from any published application(s) for said Patent Property. ASSIGNOR further assigns to and authorizes said ASSIGNEE to file corresponding applications for Letters Patent in all countries, to be held and enjoyed by said ASSIGNEE, its successors, assigns, nominees or legal representatives, to the full end of the term or terms for which said Letters Patent respectively may be granted, reissued or extended, as fully and entirely as the same would have been held and enjoyed by ASSIGNOR had this assignment, sale and transfer not been made.

It is hereby covenanted that ASSIGNOR has full right to convey the entire interest herein assigned, and that ASSIGNOR has not executed and will not execute any agreement in conflict herewith, and ASSIGNOR further covenants and agrees that it will each time request is made and without undue delay, execute and deliver all such papers as may be necessary or desirable to perfect the title to said Patent Property in said assignee, its successors, assigns, nominees, or legal representatives, and ASSIGNOR agrees to communicate to said ASSIGNEE or to its nominee all known facts respecting said Patent Property, to testify in any legal proceedings, to sign all lawful papers to execute all disclaimers and divisional, continuing, reissue and foreign applications, to make all rightful oaths, and generally to do everything reasonably possible to aid said ASSIGNEE, its successors, assigns, nominees and legal representatives to obtain and enforce for its or their own benefit proper patent protection for said inventions or improvements in any and all countries, all at the expense, however, of said ASSIGNEE, its successors, assigns, nominees or legal representatives.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS

DMI000338



AND ASSIGNOR hereby authorizes and requests the Commissioner of Patents and Trademarks of the United States and any official of any country or countries foreign to the United States whose duty it is to issue patents on applications as aforesaid, to issue to said ASSIGNEE, as assignee of the entire right, title and interest, any and all Letters Patent for said Patent Property, including any and all Letters Patent of the United States which may be issued and granted on or as a result of any applications included in said Patent Property, in accordance with the terms of this assignment.

IN WITNESS WHEREOF, the undersigned, being properly authorized to execute this Assignment, hereunto sets their hand and seal.

Ethicon, Inc.

By: Matthew S. Goodwin
Matthew S. Goodwin

Its: _____
Assistant Secretary

Date: August 9, 2004

STATE OF New Jersey :
COUNTY OF Middlesex : SS

On this 9th day of August, year of 2004, before me, the undersigned officer, personally appeared Matthew S. Goodwin who acknowledged himself/herself to be the Asst. Secy. of Ethicon Inc. a corporation, and that he/she as such Asst. Secy. being authorized to do so, executed the foregoing instrument for the purposes therein contained by signing the name of the corporation by himself/herself as Asst. Secy.

Jacqueline S. Retkwa
Notary Public

JACQUELINE S. RETKWA
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES APRIL 10, 2006

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS

DePuy Mitek, Inc.

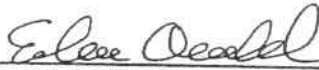
By: 
Laurence Rickles

Its: _____
Assistant Secretary

Date: August 9, 2004

STATE OF New Jersey :
: SS
COUNTY OF Middlesex :

On this 9th day of August, year of 2004, before me, the undersigned officer, personally appeared Laurence Rickles, who acknowledged himself/herself to be the Assistant Secretary of DePuy Mitek, Inc., a corporation, and that he/she as such Assistant Secretary, being authorized to do so, executed the foregoing instrument for the purposes therein contained by signing the name of the corporation by himself/herself as Assistant Secretary.


Notary Public

EDNA ARNOLD
A NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES 9/27/2006

EXHIBIT 8



US005314446A

United States Patent [19]**Hunter et al.**[11] **Patent Number:** **5,314,446**[45] **Date of Patent:** **May 24, 1994**[54] **STERILIZED HETEROGENEOUS BRAIDS**[75] **Inventors:** Alastair W. Hunter, Bridgewater;
Arthur Taylor, Jr., Plainfield, both of
N.J.; Mark Steckel, Maineville, Ohio[73] **Assignee:** Ethicon, Inc., Somerville, N.J.[21] **Appl. No.:** **838,511**[22] **Filed:** **Feb. 19, 1992**[51] **Int. Cl.⁵** **D04C 1/00**[52] **U.S. Cl.** **606/231; 606/228;**
87/7; 87/9; 428/370[58] **Field of Search** 606/228, 230, 231;
87/7, 8, 9; 428/225[56] **References Cited****U.S. PATENT DOCUMENTS**

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136

4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

FOREIGN PATENT DOCUMENTS

2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom	
2218312A	11/1989	United Kingdom	A01K 91/00

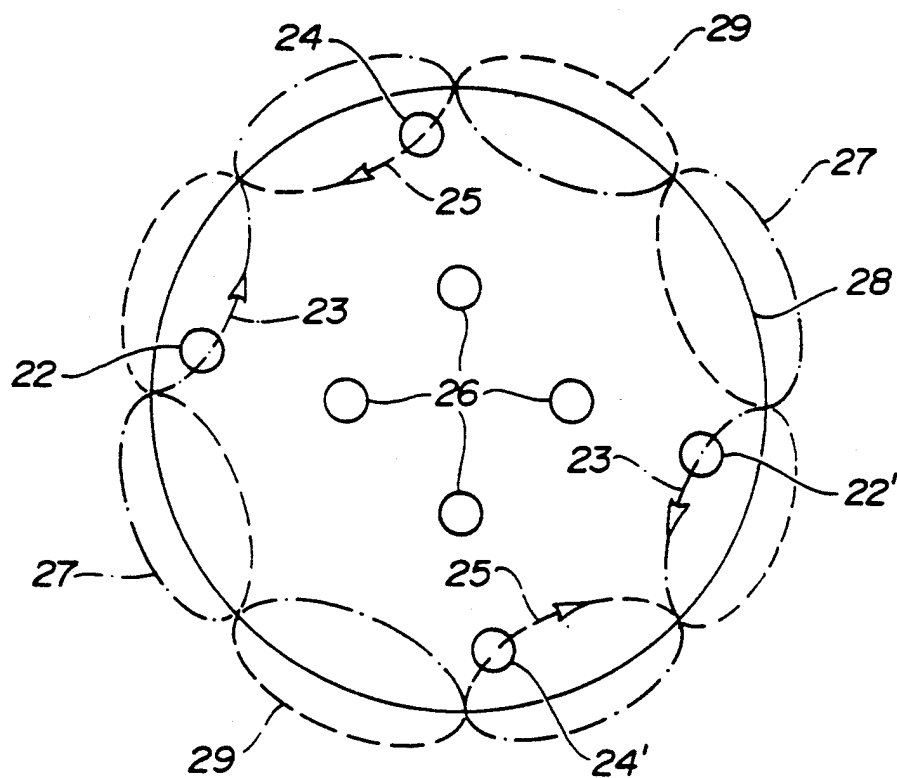
Primary Examiner—George F. Lesmes*Assistant Examiner*—Chris Raimund*Attorney, Agent, or Firm*—Hal Brent Woodrow[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1



U.S. Patent

May 24, 1994

Sheet 2 of 3

5,314,446

FIG-2

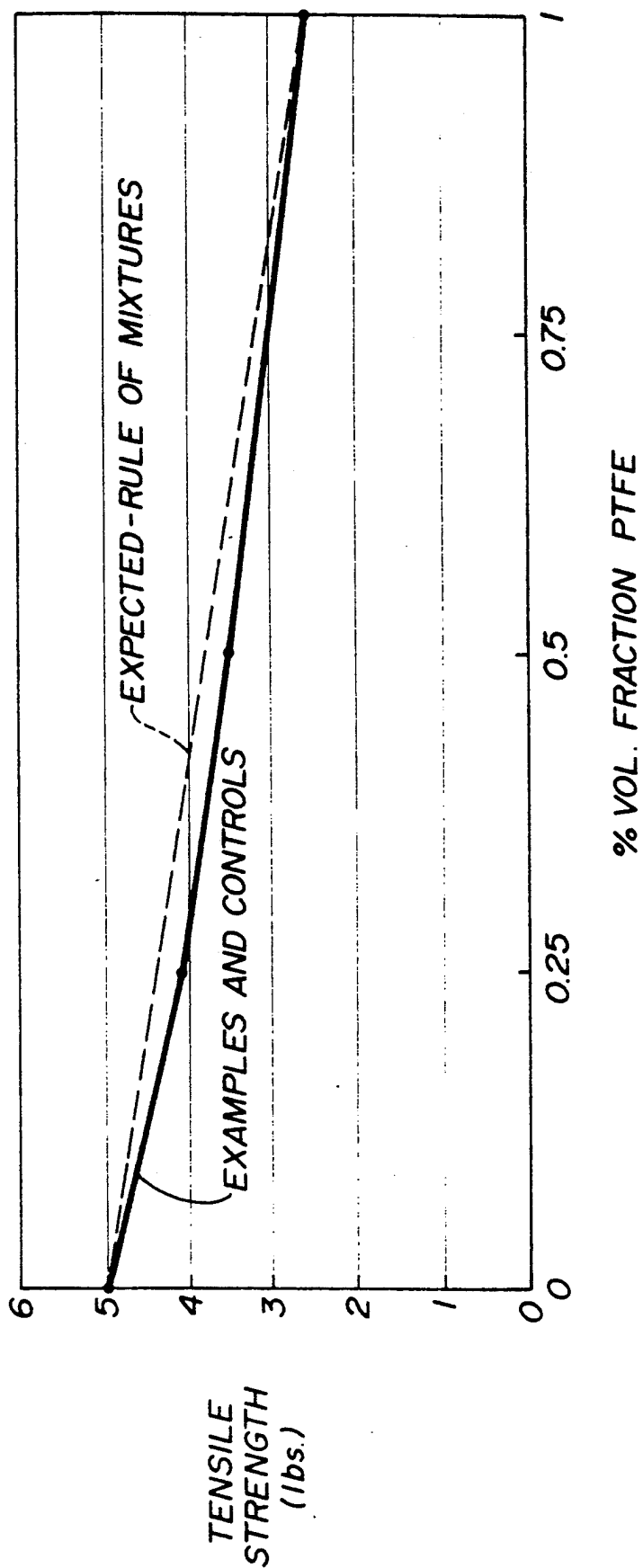
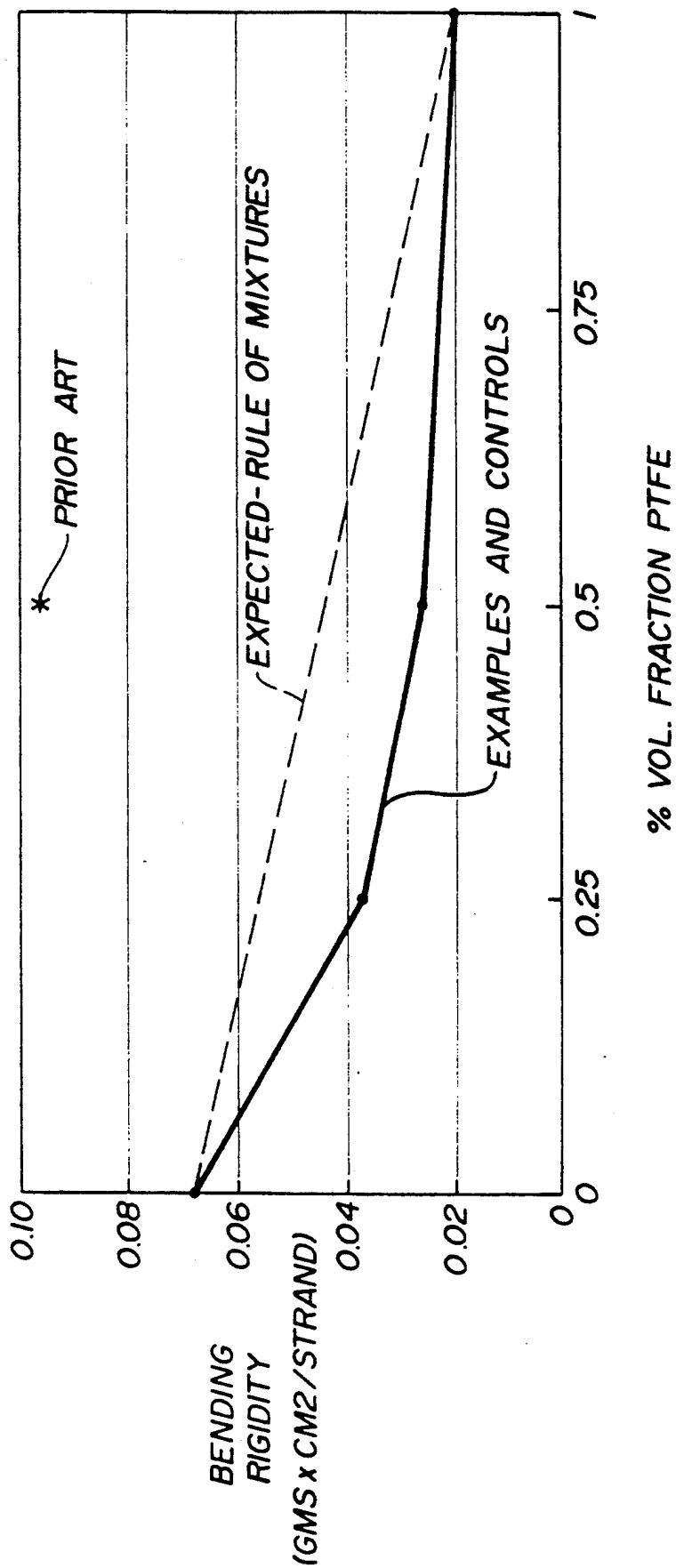


FIG-3



5,314,446

1

STERILIZED HETEROGENEOUS BRAIDS**BACKGROUND OF THE INVENTION**

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

2

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

5,314,446

3

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

4

ϵ -caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Dekker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluoroethylene copolymers (PETFE), the polychlorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

5,314,446

5

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

6

braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, then the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

7

5,314,446

8

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm ²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (V_f a) (P_a) + (V_f b) (P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and $V_f a$ and $V_f b$ are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

5,314,446

9

10

- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
- b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
- c) optionally a core.
2. The surgical suture of claim 1 wherein the suture is attached to a needle.
3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.
4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.
5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.
6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.
7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.
8. The surgical suture of claim 1 wherein the second set of yarns is PET.
9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.
10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.
11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.
12. The surgical suture of claim 8 wherein the suture is attached to a needle.
- * * * * *

25

30

35

40

45

50

55

60

65

EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff.)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation)	
)	
Defendant.)	

DePuy Mitek's Responses To Arthrex, Inc.'s First Set of Interrogatories

General Objections

1. DePuy Mitek objects to Arthrex's definitions and instructions to the extent they purport to enlarge, expand, or alter in any way the plain meaning and scope of any specific request, on the ground that such enlargement, expansion, or alteration renders said request vague, ambiguous, unintelligible, unduly broad, and uncertain.
2. DePuy Mitek objects to Arthrex's "instructions" including, but not limited to Arthrex's instructions nos. 1, 3, 4, 5, 6, and 9, as overbroad, unduly burdensome and demanding discovery obligations beyond those authorized by the Federal Rules of Civil Procedure and the Court's Local Rules. DePuy Mitek responds to Arthrex's discovery requests in accordance with the Federal Rules of Civil Procedure and the Court's Local Rules, not in accordance with Arthrex's unauthorized demands.
3. DePuy Mitek objects to Arthrex's definition of "DePuy Mitek" as overbroad and unduly burdensome. DePuy Mitek, Inc. is the only party to this action and it will respond to discovery requests in accordance with the Federal Rules of Civil Procedure and the Court's Local Rules. Neither Ethicon, Inc. nor any other Johnson and Johnson Company is a party to this action, and

Interrogatory No. 3

State with specificity and particularity every DePuy Mitek (as defined above) product that DePuy Mitek believes embodies, and/or includes at least in part, the subject matter of the '446 Patent, and for each such product, identify the earliest date on which such product was sold and/or offered for sale, state whether and how Plaintiff DePuy Mitek, Inc. is currently marking each such product to indicate that the product is covered by the '446 Patent, when Plaintiff DePuy Mitek, Inc., began such marking and whether such marking has been continuous, and if not, when such marking ended; state whether and how Ethicon, Inc. is currently marking each such product, when Ethicon, Inc. began such marking and whether such marking has been continuous from the date the '446 Patent issued, and if not, when such marking ended; identify all documents referring or relating to the subject matter of this interrogatory, and identify the three persons currently and/or formerly within DePuy Mitek's employ who are believed to be the most knowledgeable with respect to the subject matter of this interrogatory.

Response to Interrogatory No. 3

DePuy Mitek objects to this interrogatory to the extent that it demands information that is immune from discovery on the basis of the attorney-client privilege, the work-product doctrine, or Rule 26(b)(4)(B) immunity.

DePuy Mitek objects to this interrogatory as overbroad and unduly burdensome, ambiguous, and unintelligible because of its improper definition of DePuy Mitek. It demands an answer from companies and persons other than DePuy Mitek. DePuy Mitek is the only plaintiff in this action and therefore, no other company or person is answering this interrogatory. Further, to the extent that it requests information regarding Ethicon products, DePuy Mitek will answer based on its knowledge, but DePuy Mitek is not in possession, custody, or control of Ethicon and

can only answer to the extent of its knowledge concerning Ethicon products, and any statements made by DePuy Mitek are its statements, not Ethicon, Inc.'s statements.

DePuy Mitek objects to this interrogatory and the phrases "specificity and particularity" and "embodies, and/or includes at least in part, the subject matter of the '446 patent" as vague, unintelligible, overbroad, unduly burdensome, and demanding discovery that is irrelevant to any pled claim or defense and not likely to lead to the discovery of admissible evidence. DePuy Mitek construes this interrogatory as requesting information regarding DePuy Mitek's products that DePuy Mitek contends are within the scope of any claim of the Hunter patent and answers in accordance with that construction.

DePuy Mitek also objects to this request to the extent it calls for a legal conclusion and expert opinion.

DePuy Mitek objects to the phrase "all documents referring or relating to the subject matter of this interrogatory" as overbroad, unduly burdensome, and demanding information that is not reasonably calculated to lead to the discovery of admissible evidence or relevant to any pled claim or defense.

Subject to its general and specific objections and without waiving them and based on the information currently available to it, DePuy Mitek states that it does not sell a product that embodies the subject matter claimed in the '446 patent. DePuy Mitek further states that based on the information available to it, Ethicon does not sell a product that embodies the subject matter claimed in the '446 patent.

Dated: 4/4/05

DEPUY MITEK, INC.,

By its attorneys,


Dianne B. Elderkin

Lynn A. Malinoski

Michael J. Bonella

Erich M. Falke

WOODCOCK WASHBURN LLP

One Liberty Place - 46th Floor

17th and Market Streets

Philadelphia, PA 19103

(215) 568-3100

Daniel J. Gleason (BBO #194900)

Michelle Chassereau Jackson (BBO #654825)

Nutter McClennen & Fish LLP

World Trade Center West

155 Seaport Boulevard

Boston, MA. 02210-2604

617-439-2000

EXHIBIT 10

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

COPY

-----x
DePUY-MITEK, INC.,

A Massachusetts Corporation,
Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,
Defendants.
-----x

DEPOSITION OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

June 27, 2006

Reported by:

CONSTANCE S. KENT, CSR, RPR

JOB NO.: 350

1 invention during the time you were working at US
2 Surgical?

3 MR. BONELLA: Object to the form.

4 THE WITNESS: I don't recall.

5 BY MR. SABER:

6 Q. Would this definition of braid or
7 braided that you used in this patent result in yarns
8 that are in direct intertwining contact as you
9 understand that term from the '446 patent?

10 A. It's my opinion that the -- that the
11 sheath yarns would be in direct intertwining
12 contact.

13 Q. Now, in -- in your patent, this
14 definition of braid or braided didn't require that
15 there be a core, correct?

16 A. It did not require that there be a
17 core, that is correct.

18 Q. And the -- on column three, line ten,
19 it says the braided suture of this invention can
20 optionally possess in addition to the braided
21 structure itself a core component around which the
22 braid is constructed?

23 A. Yes.

24 Q. Is that correct?

25 A. That's correct, that's what it reads.

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 197

1 Q. Do you agree that Figure 6 is an
2 elongated member?

3 A. Yes, I do.

4 Q. And same thing about Figure 8?

5 A. Yes, I -- yes, sir.

6 Q. Okay. You would agree that this
7 patent discloses elongated members that are sutures,
8 correct?

9 A. I would agree that this patent
10 discloses elongated members, some of which are
11 described as sutures, yes.

12 Q. Let's go back to claim one, column
13 eight.

14 A. Yes, sir.

15 Q. Would you agree with me that the
16 first fiber includes ultra high molecular weight
17 polyethylene?

18 A. Claim one?

19 Q. Yes, sir.

20 A. Yes. It says ultra high molecular
21 weight, high tenacity is the material.

22 Q. And under this patent, that would
23 include ultra high molecular weight polyethylene?

24 A. If that's a question, I believe it
25 would, yes.

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 198

1 Q. Okay. And now there's also -- the
2 ultra high molecular weight polyethylene in claim
3 one is braided with a second fiber, correct?

4 A. That is correct.

5 Q. And could you look to claim 11?

6 A. Yes.

7 Q. And does claim 11 -- would you agree
8 with me that claim 11 says that the second fiber
9 that's braided with the ultra high molecular weight
10 polyethylene is nylon?

11 A. Yes.

12 Q. Could you look at claim 12?

13 A. Yes.

14 Q. Would you agree with me that that
15 says that the second fiber braided with the ultra
16 high molecular weight polyethylene is polyester?

17 MR. BONELLA: Object to the form.

18 THE WITNESS: Yes.

19 BY MR. SABER:

20 Q. Is there -- in claim one, is there
21 any mention of a core?

22 A. No.

23 Q. In claim 11, is there any mention of
24 a core?

25 A. No.

1 together and there's no core, that that's one of the
2 things that falls within claim 11?

3 MR. BONELLA: Object to the form.

4 THE WITNESS: Yes.

5 BY MR. SABER:

6 Q. Okay. And same thing with respect to
7 claim 12?

8 A. Yes.

9 MR. BONELLA: Object to the form.

10 THE WITNESS: I'm sorry. Yes.

11 BY MR. SABER:

12 Q. The -- could you look back at Figure
13 6?

14 A. Yes.

15 Q. Are the -- the various yarns 26 that
16 are shown in Figure 6, are they in direct
17 intertwining contact with each other?

18 A. It's my opinion that -- yarns 26 as
19 described in --

20 MR. BONELLA: Object to the form of
21 the question.

22 MR. SABER: Let me rephrase it.

23 BY MR. SABER:

24 Q. Do you agree that the yarns 26 --
25 that are denoted as 26 in Figure 6?

6/27/2006 Hermes, Matthew

1 A. Yes.

2 Q. Right? That those yarns are in
3 direct intertwining contact as that term is used in
4 the '446 patent?

5 A. I believe they are, yes.

6 Q. Let me ask you about Figure 8. Do
7 you see the yarns denoted by the numbers 30?

8 A. Yes.

9 Q. Do you agree that the yarns denoted
10 by number 30, Figure 8, are in direct intertwining
11 contact with each other as that term is used in the
12 '446 patent?

13 A. I believe that they're in direct
14 intertwining contact with each other as sheath
15 yarns. The core yarn is not.

16 Q. Well, the 30s are all in the sheath,
17 correct?

18 A. Yes, sir.

19 Q. Right. And the 30s are not in the
20 core, correct?

21 A. Yes.

22 Q. I was asking about the 30s.

23 A. Yes, sir.

24 Q. Just so the record is clear, do you
25 agree that the yarns 30 from Figure 8 are in direct

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 207

1 A. I do not have that understanding. I
2 understood your question and that is my answer.

3 Q. Okay. Assume with me that each one
4 of the yarns -- do you see in Figure 6 there are a
5 dozen or so yarns that are depicted?

6 A. Yes, sir.

7 Q. Assume with me that each one of those
8 is a 26.

9 A. We can do that.

10 Q. Okay.

11 A. Yes, sir.

12 Q. Would you agree with me that at least
13 one of those 26s is ultra high molecular weight
14 polyethylene?

15 A. Yes.

16 Q. And do you understand that more than
17 one can be ultra high molecular weight polyethylene?

18 A. Yes.

19 Q. And do you have an understanding that
20 one or more of the 26s can be a nonabsorbable yarn?

21 A. Yes.

22 Q. Let me turn to the Burgess
23 application, which is Exhibit 7 to your report, your
24 first report.

25 A. Yes, sir.

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 212

1 question, if I may.

2 Am I correct that you don't provide
3 an example of a braided construction without direct
4 intertwining contact where there is no core in your
5 report?

6 MR. BONELLA: Object to form.

7 BY MR. SABER:

8 Q. Let me rephrase that again.

9 A. Yeah, try it again.

10 Q. In your report am I correct that you
11 provide no example of a braided construction where
12 there is no direct intertwining contact of a -- of a
13 construction that does not have a core?

14 A. See if this answers your question. I
15 do not believe in my report that I provide in a
16 noncore construction a braid without intertwining
17 contact.

18 Q. Without direct intertwining contact?

19 A. Without direct intertwining contact.

20 Is that --

21 Q. That answers my question.

22 A. Is that an answer to your question?

23 Q. Yes, sir, it is.

24 A. Okay.

25 Q. And as you sit here today, can you

Deposition of:
Dr. Matthew Hermes, Vol. I

June 27, 2006

Page 213

1 give me an example of a braided construction which
2 does not have direct intertwining contact where
3 there is no core?

4 A. I'd have to think about it. I don't
5 know the answer to that.

6 Q. Okay.

7 MR. SABER: Why don't we take a break
8 at this point?

9 THE VIDEOGRAPHER: Going off the
10 record.

11 The time on the video monitor is
12 4:04 PM.

13 (Recess.)

14 THE VIDEOGRAPHER: Going back on the
15 record. The time on the video monitor is 4:24 PM.

16 Please continue.

17 BY MR. SABER:

18 Q. Dr. Hermes, I'd like to ask you a
19 little bit about the Cohan article, if I'm
20 pronouncing that correctly, which I believe is
21 Exhibit 8 to your report.

22 A. Yes, sir.

23 Q. The -- would you -- would you agree
24 with me that the Cohan article discloses the use of
25 ultra high molecular weight PE in a suture

Deposition of:
Dr. Matthew Hermes, Vol. II

July 25, 2006

Page 252

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,

6 A Massachusetts Corporation,

7 Plaintiff,

8 vs.

9 ARTHREX, INC.,

10 A Delaware Corporation,

11 Defendants.

12 _____ x

13 DAY 2 OF 2

14 CONTINUED VIDEOTAPED DEPOSITION

15 OF DR. MATTHEW HERMES

16 Philadelphia, Pennsylvania

17 July 25, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

ORIGINAL

Deposition of:
Dr. Matthew Hermes, Vol. II

July 25, 2006

	Page 346
1 marked, for identification purposes, as	01:16:47p
2 Defendant's Exhibit-194.)	01:16:48p
3 MR. BONELLA: Thank you.	01:17:18p
4 BY MR. SABER:	01:17:18p
5 Q. Let me show you Dr. -- or at least the	01:17:18p
6 second volume of Dr. Steckel's deposition, and I	01:17:23p
7 just want to draw your attention to a couple of	01:17:27p
8 pages.	01:17:29p
9 This is -- we've shown you	01:17:31p
10 what's been marked as Defendant's Exhibit-194	01:17:32p
11 which is the second volume of Dr. Steckel's	01:17:35p
12 deposition.	01:17:40p
13 A. And that's what I have, Mr. Saber,	01:17:40p
14 thank you.	01:17:44p
15 Q. Yes, sir. And if you could look at	01:17:44p
16 Page 221 of that?	01:17:46p
17 A. Okay.	01:17:48p
18 Q. You see that there's a discussion of	01:17:49p
19 the February 2, 1989, entry from his lab	01:17:53p
20 notebook?	01:17:56p
21 A. (Witness reviewing document.)	01:18:20p
22 Where's the beef?	01:19:22p
23 Q. Page 221 of his deposition --	01:19:22p
24 A. Mm-hmm, okay.	01:19:24p
25 Q. -- is where that's discussed. Do you	01:19:25p

EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation and

Pearsalls Ltd.,
a Private Limited Company
of the United Kingdom,

Defendants.

Civil No. 04-12457 PBS

Expert Report of Dr. David Brookstein

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

device “performs substantially the same function in substantially the same way to obtain the same result” (“function/way/result test”) as the claimed element.

V. Direct Infringement

A. Claim Construction

27. As mentioned above, I understand that the first step in an infringement analysis is to construe the claims. I understand that the Court will determine the meaning of the claim terms in the ‘446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

“PE” – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

“consisting essentially of” – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

“direct intertwining contact” –means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

“volume fraction of the first set of yarns in the braided sheath and core” means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHMWPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the “way” of the first fiber-forming material is the same as the “way” of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	“Way” of Limitation Under the Doctrine of Equivalents	Way UHMWPE performs its Function in FiberWire™ and TigerWire™
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The “way” is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the “way” of the “first fiber-forming” element is supported by the ‘446 Patent. The ‘446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact. For example, the ‘446 Patent states in the “Summary of the Invention” section that the “the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction” and that the at least one yarn from the first set is in “direct

EXHIBIT 12

227

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts
Corporation,
Plaintiff,
v.
ARTHREX, INC., a Delaware
Corporation,
Defendant.

Civil Action
No. 04-12457 PBS

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

**HIGHLY
CONFIDENTIAL**

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
12th January 2006

1 samples 100% -- you see later down in the letter it
2 says:

3 "Can you build a 25% Dyneema/75%
4 polyester blend in a size 2 that is very flexible
5 (like the existing suture or the ethicon sample) and
6 send it to me to test".

7 Do you see that?

8 A Yes.

9 Q In the top paragraph does the sample of
10 the Dyneema material, does that refer to a braid of
11 100% Dyneema?

12 A I can't remember.

13 Q Do you recall ever making a construction
14 that was 100% ultra high molecular weight
15 polyethylene for Arthrex?

16 A I can't remember.

17 Q In November '98 is that when FiberWire was
18 first being developed?

19 A Yes.

20 Q What did you understand Mr. Grafton to
21 mean when he said:

22 "Can you build a 25% Dyneema/75%
23 polyester blend in Size 2 that is very flexible".

24 What did you understand that to mean?

25 A Yes, that he wanted a braid which was

1 more -- not so stiff.

2 Q As the 100% ultra high molecular weight
3 polyethylene?

4 A Yes.

5 Q He wanted Pearsalls to try to put
6 polyester with --

7 A With the mixture.

8 Q With a braid. He wanted -- let me finish
9 the question before you answer.

10 Mr. Grafton wanted Pearsalls to braid
11 polyester with the ultra high molecular weight
12 polyethylene so that the polyester could provide
13 flexibility?

14 A Yes.

15 Q Next I will show you Exhibit 325. It is
16 Bates number PR 6493. Do you recognize Exhibit 325
17 as a letter from you to Mr. Grafton from November
18 1998?

19 (DePuy Mitek Exhibit 325 marked for identification)

20 A Yes.

21 Q And the letter said:

22 "Please find enclosed a matrix of
23 information of the samples that you took with you on
24 your visit to Pearsalls, I will endeavour to proceed
25 with the existing trial to match US2 Excel Braid

EXHIBIT 13

US005123913A

United States Patent [19][11] **Patent Number:** **5,123,913****Wilk et al.**[45] **Date of Patent:** * **Jun. 23, 1992**[54] **SUTURE DEVICE**

[76] **Inventors:** **Peter J. Wilk**, 185 West End Ave., New York, N.Y. 10023; **David Sekons**, 455 East 86th St., New York, N.Y. 10028

[*] **Notice:** The portion of the term of this patent subsequent to Aug. 21, 2007 has been disclaimed.

[21] **Appl. No.:** **525,157**

[22] **Filed:** **May 17, 1990**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 441,314, Nov. 27, 1989, Pat. No. 4,950,285.

[51] **Int. Cl.⁵** **A61B 17/00**

[52] **U.S. Cl.** **606/232; 606/224; 606/151; 24/16 PB; 24/17 AP**

[58] **Field of Search** **606/131, 139, 224, 232, 606/233, 231; 24/17 AP, 16 PB, 30.5 P**

[56] **References Cited****U.S. PATENT DOCUMENTS**

1,848,318 3/1932 Ciampi 24/713
 3,072,986 1/1963 Lefnaer 24/16 PB
 3,570,497 3/1971 Lemole 606/228
 3,597,803 8/1971 Van Neil 24/16 PB
 3,625,220 12/1971 Engelsher 606/233
 3,831,608 8/1974 Kletscka et al. 606/233

3,985,138 10/1976 Jarvik 606/231
 4,038,725 8/1977 Keefe 24/16 PB
 4,069,825 1/1978 Akiyama 606/174
 4,741,330 5/1988 Hayhurst 606/86
 4,813,416 3/1989 Pollak et al. 606/151

FOREIGN PATENT DOCUMENTS

2301717 9/1976 France 24/16 PB
 903599 9/1962 United Kingdom 24/30.5 P

OTHER PUBLICATIONS

Photographic representations of three commercially available tie devices.

Primary Examiner—Stephen C. Pellegrino

Assistant Examiner—Gary Jackson

Attorney, Agent, or Firm—R. Neil Sudol; Henry D. Coleman

[57] **ABSTRACT**

A suture device comprises a loop member formed on one side with an aperture and an access channel extending from the aperture to an opening defined by the loop. A thread connected to loop is provided along a portion of its length with a series of tapered projections. Protuberances are provided on the loop member along the access channel between the opening and the aperture for preventing a return of the thread through the channel upon a passing of the thread through the loop and subsequently through the channel into the aperture.

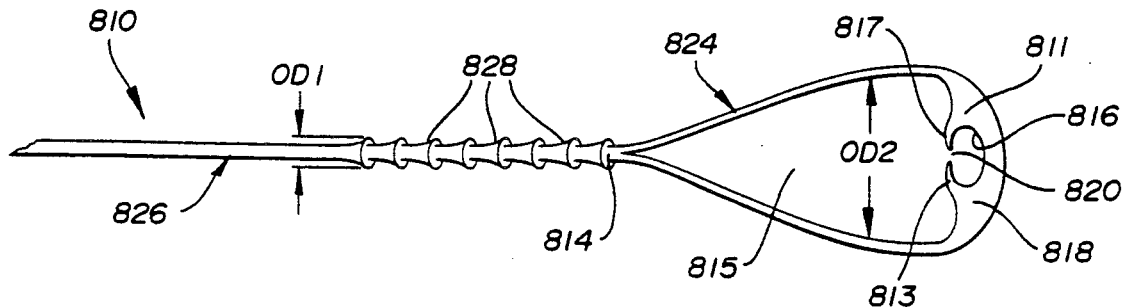
28 Claims, 6 Drawing Sheets

FIG-1

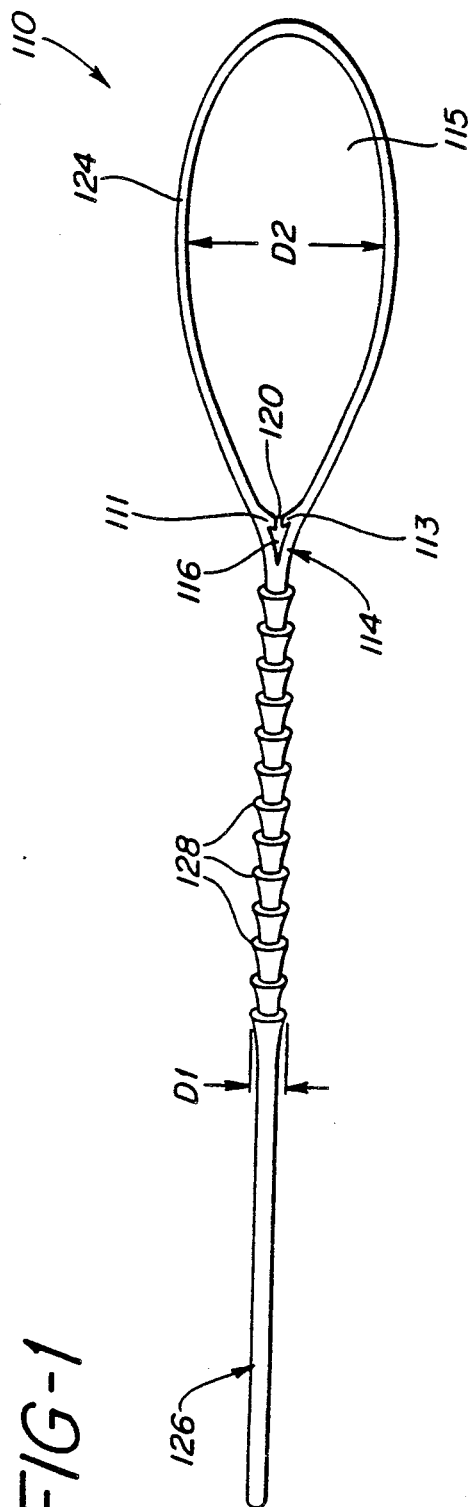


FIG-2

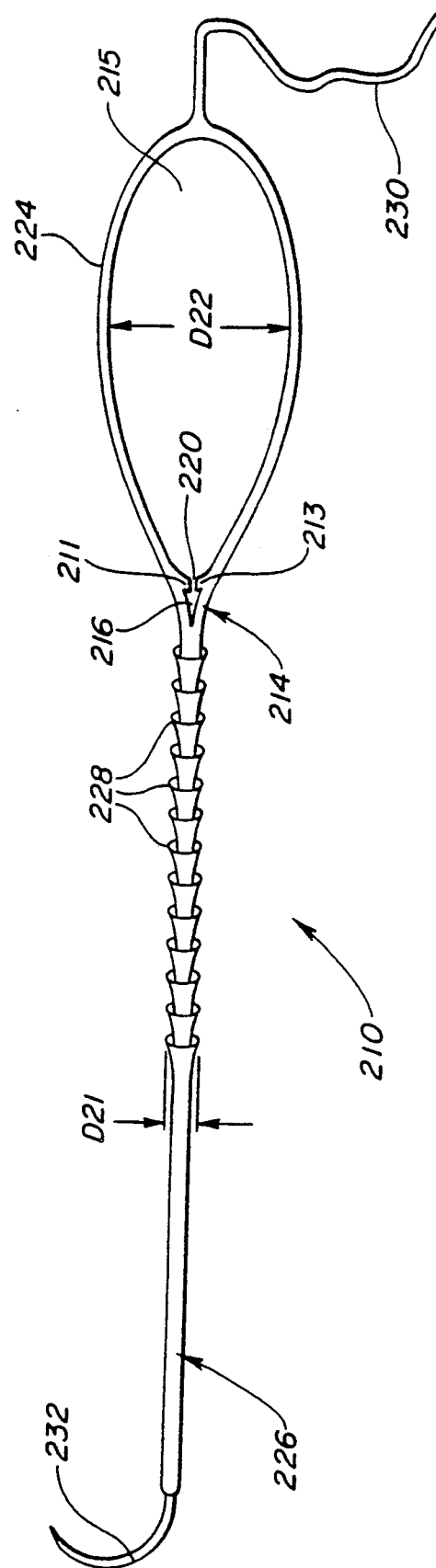


FIG-3

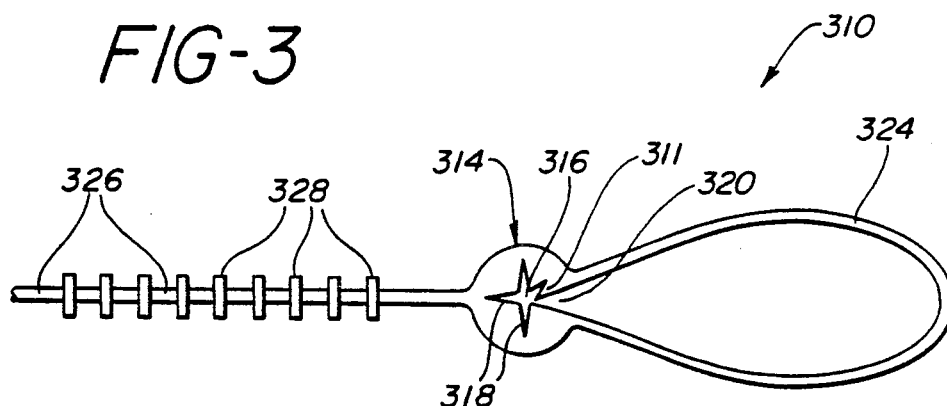


FIG-4

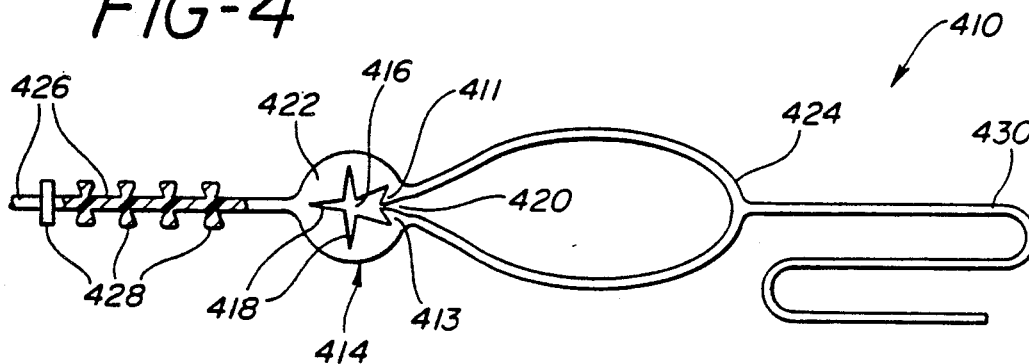


FIG-5

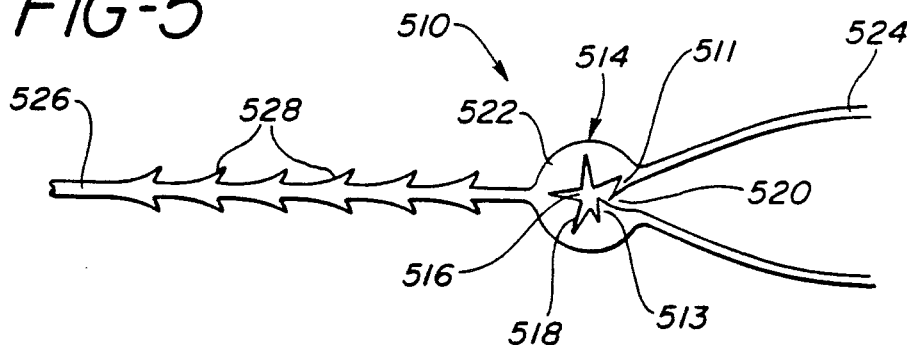


FIG-6

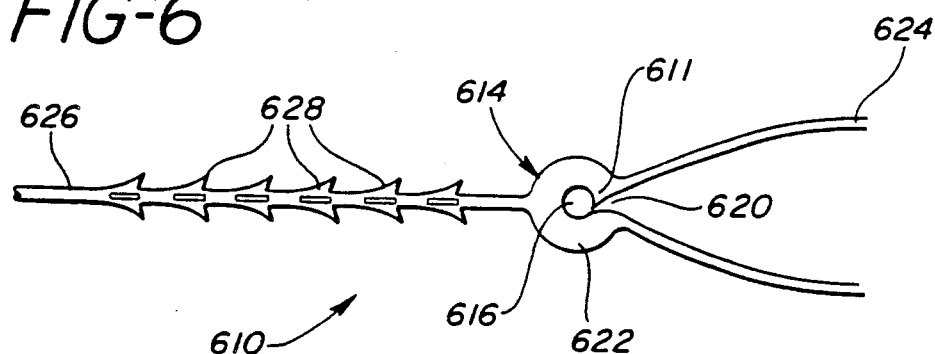


FIG-7

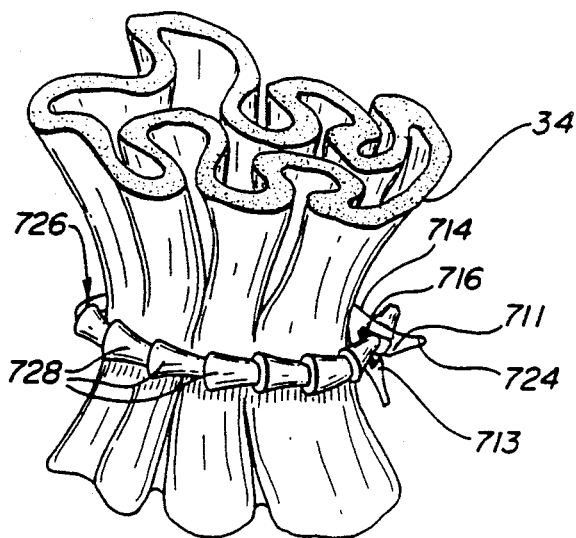


FIG-8A

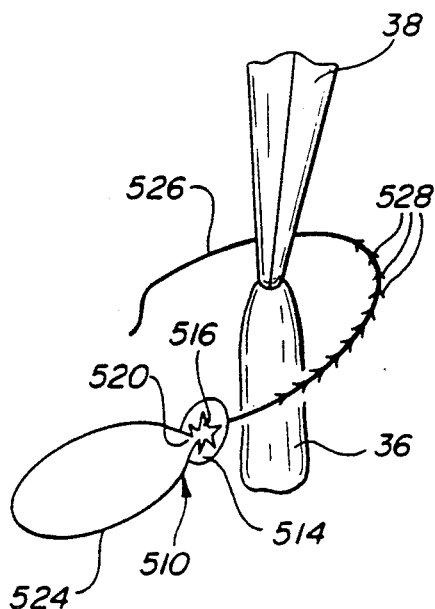


FIG-8B

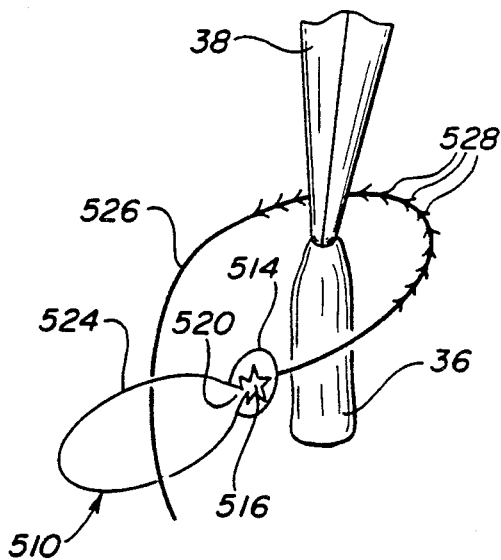


FIG-8C

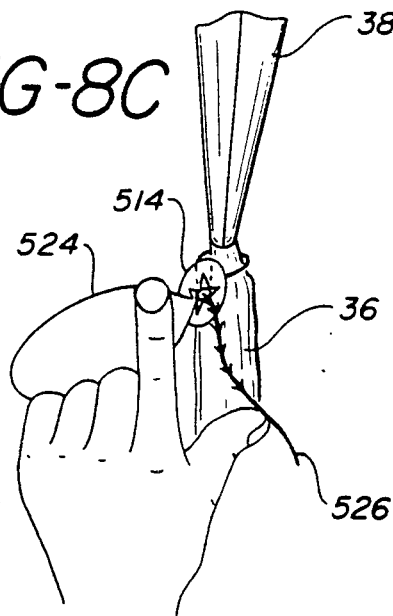
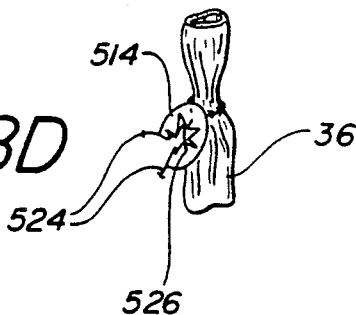
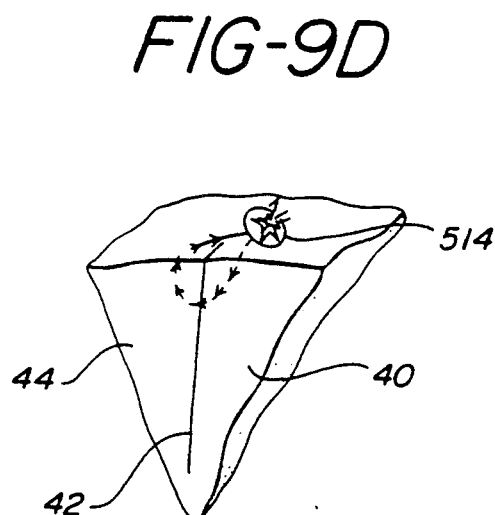
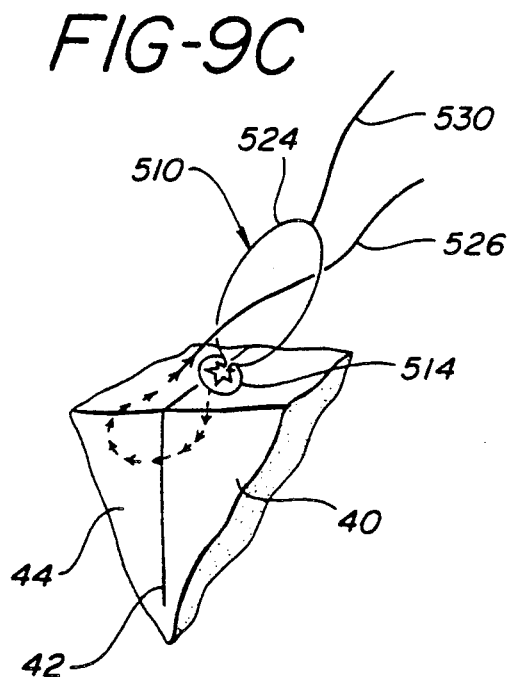
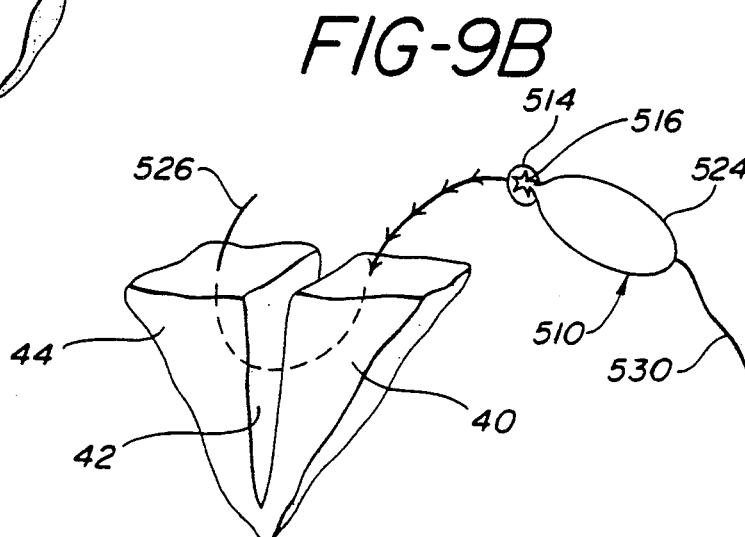
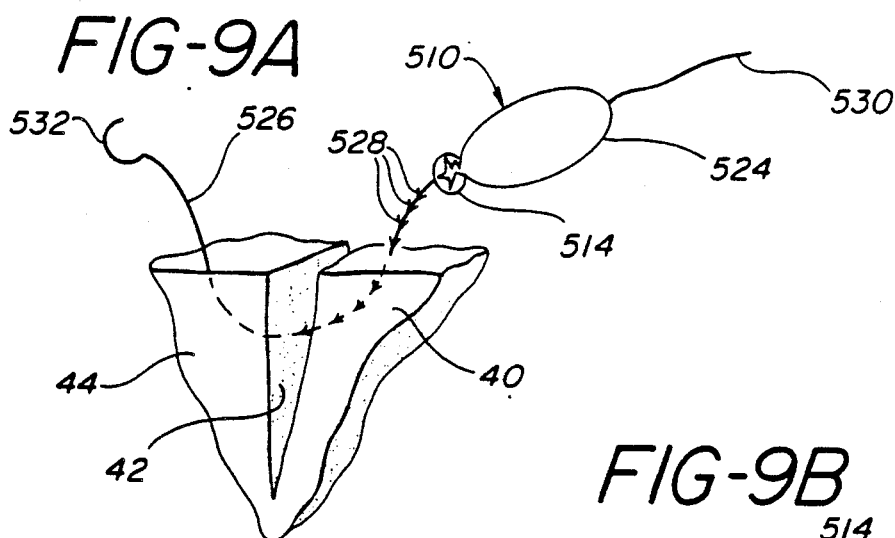


FIG-8D





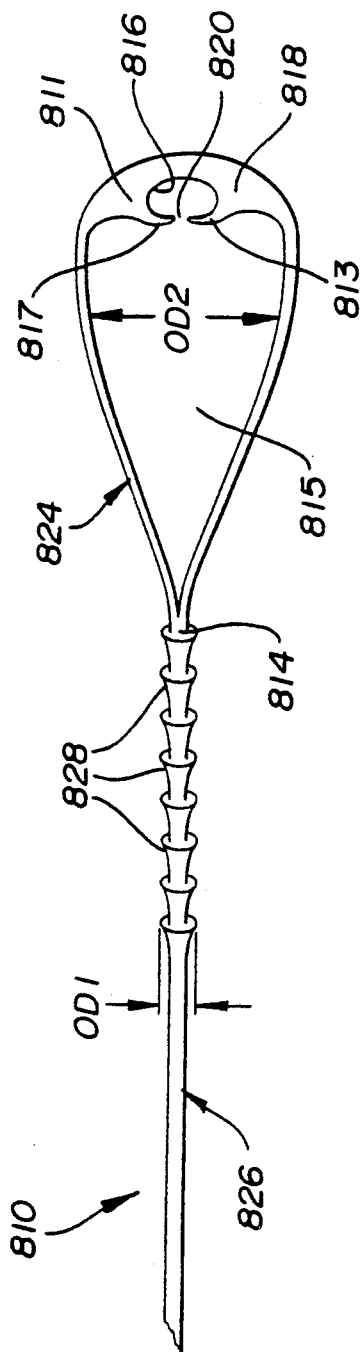


FIG-10

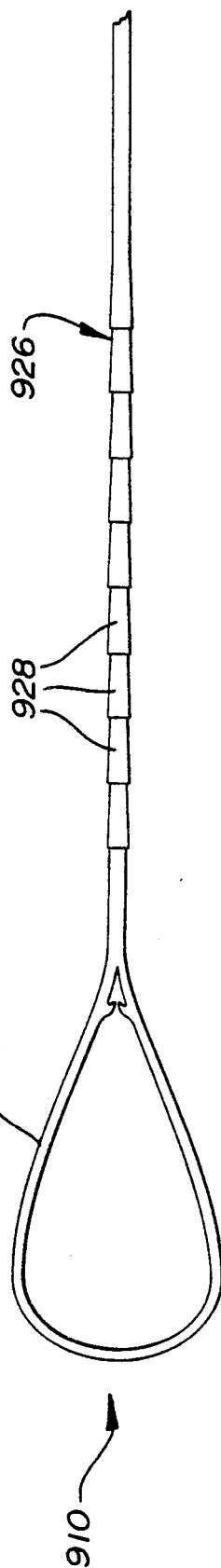


FIG-11

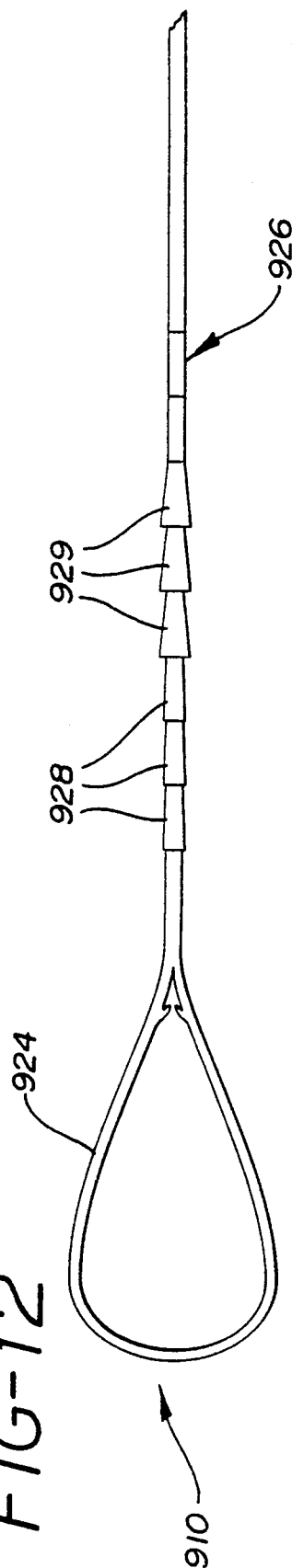


FIG-12

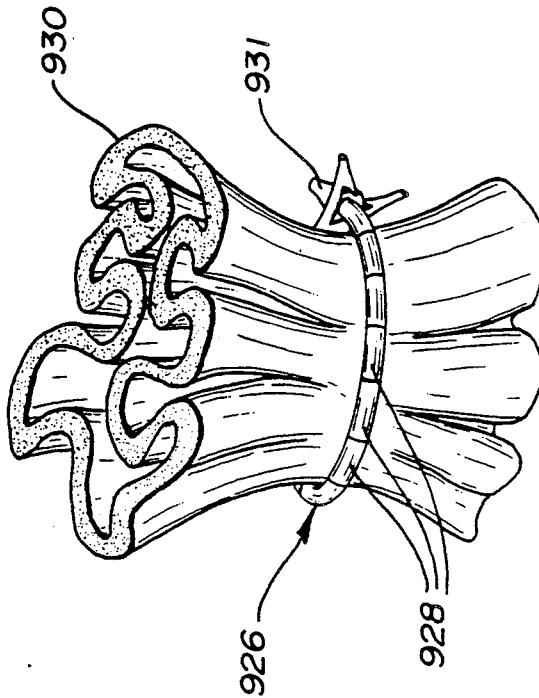


FIG-13

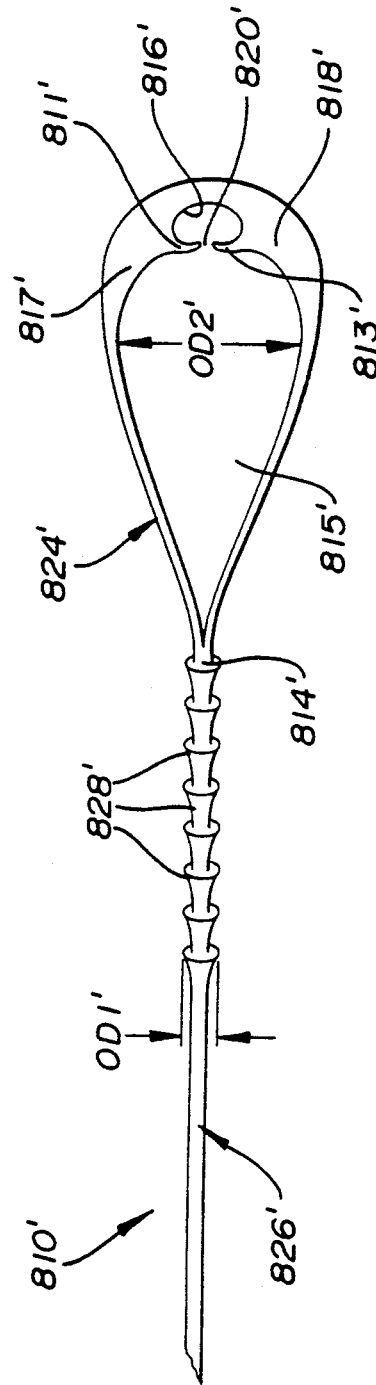


FIG-14

5,123,913

1

SUTURE DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in part of application Ser. No. 441,314 filed Nov. 27, 1989 now U.S. Pat. No. 4,950,285.

BACKGROUND OF THE INVENTION

This invention relates to a suture device. More particularly, this invention relates to a suture device with components for locking the suture upon the application thereof at a surgical site.

As described in U.S. Pat. No. 3,570,497 to Lemole, a suture apparatus includes a cord of latch notches, a needle at one end of the cord, and a latch collar at the other end of the cord. The latch collar is provided with a passage through which the needle is pulled, followed by a selected number of latch notches. Upon the pulling of a final notch through the collar passage, the cord is severed on a side of the latch collar opposite the side of entry of the cord into the latch passage.

Although the suture device of U.S. Pat. No. 3,570,497 provides a number of advantages over simple suture threads, that suture device has several shortcomings which make it unsuitable for many surgical applications. Particularly in cases requiring fine stitches or ligatures, where the device of Lemole is necessarily small, the needle and cord of that device are inserted through the passage in the latch collar only with appreciable difficulty. Although in some applications, such as in the binding of a sternum or the approximating of ribs, a large suture device is necessary to provide the requisite strength, in other applications complications may arise by leaving a large suture structure at the surgical site.

U.S. Pat. No. 4,069,825 to Akiyama discloses a ligature including a surgical thread with a plurality of spherical or conical projections spaced regularly along the length of the thread. One end of the thread is attached to a cylindrical member having an aperture with a diameter larger than the outside diameter of the projections on the thread. The spacings between the projections and the size of the apertured member are designed to enable a locking of the thread in a loop about a vessel by means of friction forces which arise between the projections and the apertured member upon a passing of the thread through the aperture and a subsequent tightening of the loop so formed.

The ligature disclosed in Akiyama suffers from the same disadvantages as the suture device of Lemole. Basically, in cases where fine blood vessels or other ducts are to be closed, the passing of the thread through the apertured member is difficult and requires considerable concentration and patience.

As depicted in U.S. Pat. No. 3,985,138 to Jarvik, another ligature comprises an endless loop formed with a continuous series of ratchet-like ridges or pawl-like teeth. One side of the loop is connected via an elongate extension to a finger engaging loop, the extension traversing an opening in a closure member. Upon a pulling of the ridged loop through the closure by means of the finger engaging loop, the ridged loop is constricted and the teeth along the endless loop are caught against the closure to lock the endless loop in its constricted configuration.

Although the ligature of Jarvik obviates the problem of passing a thread through a small opening, the endless

2

ridged or toothed loop must generally be passed over the end of a hemostat prior to closure of that loop about a severed blood vessel. This step clearly complicates the ligation procedure. In addition, the closure of the Jarvik ligature is necessarily bulky.

OBJECTS OF THE INVENTION

An object of the present invention is to provide a suture device of the above-described general type which can be used in both ligating and suturing operations.

Another object of the present invention is to provide such a suture device which is easy to use, even in cases requiring a small sutures or ligatures.

Another, more particular, object of the present invention is to provide such a suture device which is easy and inexpensive to manufacture.

A further particular object of the present invention is to provide such a suture device which comprises a reduced amount of material.

SUMMARY OF THE INVENTION

A suture device in accordance with the present invention comprises a thread member, a loop member, a connector element or portion, and a locking component or components. The thread member is provided along at least a portion of its length with a series of resilient projections and has an outer diameter defined by the projections. The loop member is in the form of a flexible thread and defines an opening having an effective linear dimension or diameter (when the loop is in a circular configuration) substantially larger than the outer diameter of the thread member, while the connector element or portion serves to couple one end of the thread member to the loop member. Either the thread member or the connector element or both define at least in part an aperture having a linear dimension smaller than the outer diameter of the thread member, the aperture communicating with the opening in the loop member. The locking component or components are provided on either the connector element or the loop member or both and serve to prevent a removal of the thread member from the aperture upon a passing of the thread member through the loop member and a subsequent pulling of the thread member into the aperture from the loop member.

In using a suture device in accordance with the invention, a surgeon passes a free end of the thread member through or around a body tissue or organ to be sutured or ligated. Subsequently, the free end of the thread is passed through the loop member so that the thread member forms another loop. The surgeon then pulls the thread member through the loop member so that the thread member passes the locking component(s) into the aperture and so that the loop formed by the thread contracts. Upon the surgeon's continuing to pull the thread member through the aperture, the thread loop is tightened about the body tissue or organ to be sutured or ligated. The locking components automatically prevent the thread member from being withdrawn from the aperture. In a final step of a method, a free end portion of the thread member is severed and removed from the fastened suture upon a completion of the thread pulling operation.

In an optional, additional step of a method pursuant to the present invention, upon a completing of the thread pulling operation, the loop member is severed

5,123,913

3

from the connector element. To enable performance of this step, the method must use a particular suture according to the invention wherein the aperture is contiguous with the connector element and is therefore located on the same side of the loop member as the connector element.

Pursuant to preferred features of the present invention, a locking component is in the form of a protuberance on the loop and projects towards the aperture. Preferably, there are two locking components in the form of two protuberances projecting from the loop towards the aperture. The protuberances are undercut on a side facing the aperture, with the result that they appear to lean inwardly towards the aperture.

The protuberances may be disposed across an access channel from one another or may be staggered along the channel, the channel communicating on the one side with the loop opening and on the other side with the aperture.

Pursuant to another feature of the present invention, the connector element comprises a Y-shaped connector piece between the thread member and the loop member.

Pursuant to yet another feature of the present invention, the loop member is provided on a side opposite the connector element and the thread member with an extension such as an additional thread member. This extension facilitates the positioning of the loop member to receive the thread member. A surgeon uses the thread to hold the loop member out and away from the body tissues being sutured or ligated.

In accordance with a preferred embodiment of the present invention, the aperture is generally triangular.

In accordance with another, particular embodiment of the present invention, the connector element comprises a body member between the loop member and the thread member, the body member being formed with the aperture. In a preferred form, the body member is cylindrical, while the aperture is star-shaped.

Pursuant to yet further features of the present invention, the projections on the thread member are tapered from a larger transverse dimension down towards an end of the thread member opposite the connector element, while the thread member, the loop member, the connector element and the locking component or components are integrally molded. Advantageously, a needle element is attached to the thread member at an end thereof opposite the connector element.

A suture device in accordance with an embodiment of the present invention has a body member which defines the aperture for receiving the thread member. In this embodiment of the invention, the thread member is connected to one side of the body member, while the loop member is connected to another side of the body member substantially opposite the thread member. In addition, the body member is provided with an access channel extending between the loop member and the aperture and is further provided with the locking component or components for preventing a removal of the thread member from the aperture upon a threading of the thread member through the loop member and a subsequent pulling of the thread member through the access channel into the aperture from the loop member.

In accordance with another particular embodiment of the present invention, a suture device comprises a thread member provided along at least a portion of its length with a series of resilient projections, the thread member having an outer diameter defined by the projections. A loop member defines an opening having a

4

linear dimension substantially larger than the outer diameter, while a connector component or portion joins one end of the thread member to the loop member. An aperture forming component is provided on the loop member along a portion thereof spaced from the connector component for defining an aperture having a linear dimension smaller than the outer diameter of the thread member and communicating with the opening defined by the loop. At least one locking component is provided for preventing a removal of the thread member from the aperture upon a passing of the thread member through the loop member and a subsequent pulling of the thread member into the aperture from the loop member. The locking component advantageously takes the form of at least one protuberance on the loop member or the aperture forming component, the protuberance pointing from the loop opening towards the aperture.

A suture device in accordance with the present invention is easy to use, particularly in cases requiring a small sutures or ligatures. The suture device may in such cases comprise a comparatively small amount of material. And such a suture device can be used in both ligating and suturing operations, in microsurgery and possibly neurosurgery, as well as in more conventional applications such as ligation of blood vessels and other ducts and approximation of ribs and the binding of sternums.

A suture device in accordance with the present invention provides a suture which is virtually slippage free, even in cases where considerable amounts of stress and tension are involved. Such a suture device enables or at least facilitates the application of higher magnitudes of force to provide tighter bonds, closures and ligations.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a side elevational view of a suture device in accordance with the present invention.

FIG. 2 is a side elevational view of another suture device similar but not identical to the suture device of FIG. 1.

FIG. 3 is a partial side elevational view, on an enlarged scale, of another suture device in accordance with the present invention.

FIG. 4 is a partial side elevational view, on an enlarged scale, of yet another suture device in accordance with the present invention.

FIGS. 5 and 6 are partial side elevational views of additional suture devices in accordance with the present invention.

FIG. 7 is a perspective view, on an enlarged scale, of another embodiment of a suture device in accordance with the present invention, upon use thereof in ligating a blood vessel.

FIGS. 8A through 8D are schematic perspective views showing successive steps in using a suture device in accordance with the present invention, for ligating a vessel or duct.

FIGS. 9A through 9D are schematic perspective views showing successive steps in using a suture device in accordance with the present invention, for closing a wound or cut in a body tissue or organ.

FIG. 10 is a partial side elevational view of an additional suture device in accordance with the present invention.

5,123,913

5

FIG. 11 is a partial side elevational view of yet another suture device in accordance with the present invention.

FIG. 12 is a partial side elevational view of the suture device of FIG. 11, showing a pair of expanded conical projections along a thread member.

FIG. 13 is a perspective view of the suture of FIGS. 11 and 12, in use in the ligating of a blood vessel.

DETAILED DESCRIPTION

As illustrated in FIG. 1, a suture device 110 comprises a thread member 126, a loop member 124, a connector element 114, and a locking mechanism in the form of a pair of inwardly projecting resilient protuberances 111 and 113 on loop member 124. Thread member 126 is formed along a portion of its length with a series of conically tapering projections 128 and has an outer diameter D1 defined by a maximum outer transverse dimension of projections 128. Projections 128 each taper from the maximum outer transverse dimension on a side facing connector element 114 to a minimum transverse dimension at the adjacent projection.

Loop member 124 defines an opening 115 having an effective linear dimension or overall diameter D2 (when the loop is circularly arranged) substantially larger than outer diameter D1 of thread member 126. Connector element 114 is in the shape of a Y and serves to couple one end of thread member 126 to loop member 124. Loop member 124, connector element 114 and protuberances 111 and 113 define a generally triangular aperture 116 having a linear dimension or size smaller than outer diameter D1 of thread member 126. Generally, aperture 116 has an area smaller than the cross-sectional area of projections 128 at the large ends thereof. Protuberances 111 and 113 are undercut on a side facing aperture 116, with the result that the protuberances appear to lean inwardly towards the aperture.

Linear dimension or overall diameter D2 of loop member opening 115 is at least twice as large as outer diameter D1 of thread member 126. Concomitantly, opening 115 of loop member 124 has an area at least four times the cross-sectional area subtended by projections 128 at their largest width or diameter. This substantial difference in the dimensions of opening 115 and thread member 126 enables practical use of the suture. If opening 115 were smaller, relative to the outer diameter D1 of thread member 126, than contemplated by the invention, the suture could not perform satisfactorily in surgical applications, inasmuch as the suture is very small. Moreover, during surgical operations surgeons wear gloves which interfere with facile manipulation of thread member 126 and loop member 124 and thus with the threading of the thread member through the loop member. The greater size of opening 115 facilitates a threading operation which otherwise could not be performed at all or could be performed only with the greatest difficulty.

For some applications of suture device 110, linear dimension or overall diameter D2 of loop member opening 115 is preferably even larger than twice outer diameter D1 of thread member 126. For example, diameter D2 may be six times the size of diameter D1. In such a case, of course, opening 115 of loop member 124 has an area at least thirty-six times the cross-sectional area subtended by projections 128 at their largest width or diameter.

Protuberances 111 and 113 define a passageway or access channel 120 between opening 115 and aperture

6

116. The protuberances serve to prevent a removal of thread member 126 from aperture 116 upon a passing of thread member 126 through opening 115 (i.e., through loop member 124) and a subsequent pulling of thread member 126 into aperture 116 from opening 115 through access channel 120.

It is to be noted that connector element 114 and protuberances 111 and 113 may be considered to form a body member to which thread member 126 on one side and loop member 124 on an opposite side are connected. Aperture 116 is provided in the body member.

As illustrated in FIG. 2, another suture device 210 similar to that illustrated in FIG. 1, also comprises a thread member 226, a loop member 224, a connector element 214, and a locking mechanism in the form of a pair of inwardly projecting resilient protuberances 211 and 213 on loop member 224. Thread member 226 is formed along a portion of its length with a series of conically tapering projections 228 and has an outer diameter D21 defined by a maximum outer transverse dimension of projections 228. Projections 228 each taper from the maximum outer transverse dimension on a side facing connector element 214 to a minimum transverse dimension on an opposite side.

Loop member 224 defines an opening 215 having an effective linear dimension or overall diameter D22 (when the loop is in a circular configuration) substantially larger than, i.e., at least twice as large as, outer diameter D21 of thread member 226. Connector element 214 is in the shape of a Y and serves to couple one end of thread member 226 to loop member 224. Loop member 224, connector element 214 and protuberances 211 and 213 define a generally triangular aperture 216 having a linear dimension or size smaller than outer diameter D21 of thread member 226. Generally, aperture 216 has an area smaller than the cross-sectional area of projections 228 at the large ends thereof.

Protuberances 211 and 213 define a passageway or access channel 220 between opening 215 and aperture 216. The protuberances serve to prevent a removal of thread member 226 from aperture 216 upon a passing of thread member 226 through opening 215 (i.e., through loop member 224) and a subsequent pulling of thread member 226 into aperture 216 from opening 215 through access channel 220.

It is to be noted that connector element 14 and protuberances 11 and 13 may be considered to form a body member to which thread member 26 on one side and loop member 24 on an opposite side are connected.

Suture device 210 differs from suture device 110 in several respects. The free end of thread member 226 is provided with a hook shaped suture needle 232, and loop member 224 is smaller than loop member 124. In addition, loop member 224 is provided on a side opposite connector element 214 with an extension thread 230, for purposes of facilitating the manipulation of loop 224 by a surgeon or other user, so that loop 224 may be held outwardly to enable easy passage of thread member 226 through opening 215. Finally, projections 228 are at least partially hollow, while projections 128 are substantially solid.

Because projections 228 are hollow, they are collapsible during a sewing stroke of thread member 226. Accordingly, thread member 226 presents a smooth or streamlined configuration to body tissues through which the thread member is being pulled during a stitching or sewing stroke. However, in accordance with the self-locking feature of suture device 210, pro-

5,123,913

7

jections 228 expand into an opened configuration upon a pulling of thread member in a reverse direction through aperture 216 after a sewing operation has been completed.

As depicted in FIG. 3, a suture device 310 comprises a body member 314 generally in the form of a small cylinder or sphere. Body member 314 is provided with a star-shaped aperture or bore 316 extending longitudinally (or diametrically, in the case of a sphere) through the body member and provided with a plurality of circumferentially or angularly spaced tapering fingers 318. One finger 320 forms an access channel extending to an opening 315 defined in a loop 326 attached to body member 314. Along access channel 320 body member 314 is provided with a resilient inwardly projecting protuberance 311.

Suture device 310 also comprises a thread 326 attached to the outer surface of body member 314 on a side thereof opposite access channel 320. The other end of thread 324 is unattached, i.e., a free end.

Thread member 326 is provided along at least a portion of its length with a multiplicity of substantially equispaced ribs 328. Ribs 328 have an outer diameter substantially smaller than a linear dimension or diameter of opening 315, whereby thread member 326 with ribs 328 easily passes through opening 315.

Protuberance 311 serves to prevent a removal of thread member 326 from aperture 316 upon a passing of thread member 326 through opening 315 (i.e., through loop member 324) and a subsequent pulling of thread member 326 into aperture 316 from opening 315 through access channel 320.

It is to be noted that connector element 114 and protuberances 111 and 113 may be considered to form a body member to which thread member 126 on one side and loop member 124 on an opposite side are connected.

FIG. 4 depicts a suture device 410 similar to suture device 310, insofar as suture device 410 also comprises a body member 414 generally in the form of a small synthetic resin or polymeric cylinder. Body member 414 is formed with a star-shaped aperture or bore 416 having several tapering fingers 418. One finger 420 is open on an outer side and extends to an outer surface 422 of body member 414. Suture device 410 also comprises a first thread 424 and a second thread 426. First thread 424 is attached at its opposite ends to outer surface 422 on opposite side of finger 420 to form a loop, while one end of second thread 426 is connected to body member 414 on a side thereof opposite finger 420. Thread 424 is provided along at least a portion of its length with a multiplicity of flattened, tire shaped ribs 428.

As depicted in FIGS. 3 and 4, the loop formed by thread 424 of suture device 410 is smaller than loop 324 of suture device 310. In addition, thread 424 is connected at a point approximately midway along its length to one end of a third thread 430. The other end of thread 430 is free.

Body member 414 is provided along finger 420 with a pair of resilient inwardly projecting protuberances 411 and 413 which serve to prevent a removal of thread member 426 from aperture 416 upon a passing of thread member 426 through an opening 415 defined by thread 424 and upon a subsequently pulling of thread member 426 into aperture 416 from opening 415 through finger 420.

As illustrated in FIG. 5, a suture device 510 comprises a body member 514 generally in the form of a small cylinder or sphere. Body member 514 is provided

8

with a star-shaped aperture or bore 516 extending longitudinally (or diametrically, in the case of a sphere) through the body member and provided with a plurality of circumferentially or angularly spaced tapering fingers 518. One finger 520 extends to an outer surface 522 of body member 514.

Suture device 510 also comprises a first thread 524 attached at its opposite ends to outer surface 522 on opposite side of finger 520 to form a loop defining an opening 515. One end of a second thread 526 is attached to outer surface 522 of body member 514 on a side thereof opposite finger 520. The other end of thread 524 is unattached.

Thread 524 is provided along at least a portion of its length with a multiplicity of barbs, teeth or serrations 528 which are inclined from the free end of thread 526 towards the attached end thereof, i.e., towards body member 514.

Body member 514 is provided along finger 520 with a pair of resilient protuberances 511 and 513 projecting inwardly towards aperture or bore 516. Protuberances 511 and 513 are staggered with respect to one another, protuberance 513 being closer than protuberance 511 to the center of aperture 516. Protuberances 511 and 513 serve the locking or blocking function described above.

As illustrated in FIG. 6, another suture device 610 in accordance with the invention includes a body member 614 with a substantially cylindrical aperture 616 communicating via a passageway or access channel 620 with a loop formed by a thread 624 attached at its ends to an outer surface 622 of body member 614 on opposite sides of channel 620. A thread 626 is connected at one end to body member 614 on a side thereof opposite channel 620 and thread 624. Thread 626 is provided along at least a portion of its length with a multiplicity of barbs, teeth or serrations 628 which are inclined outwardly from the free end of thread 626 towards body member 614. Teeth 628 are triangular and are provided in longitudinally spaced arrays of four circumferentially spaced teeth.

Body member 610 is provided in channel 620 with an inwardly directed barb, hook or fingerlike protuberance 211 which overlaps the inner end of channel 620 and acts as a one-way valve member to close that channel to the removal of thread 624 upon the lodgement thereof in aperture 616.

FIG. 7 illustrates the disposition of a suture device 710 (basically the same as suture devices 110 and 210) with respect to a blood vessel 34 upon the completion of an operation attaching the suture device to the vessel to close it. Suture device 710 includes a thread 726 provided along at least a portion of its length with a series of conically tapered projections 728. Thread 726 extends from a Y-shaped body member 714 around the circumference of vessel 34 and through a triangular aperture 716 in the body member. A free end of thread 726 is locked to body member 714 in part by a pair of protuberances 711 and 713 incorporated in body member 714. Protuberances 711 and 713 are resilient finger shaped elements defining an access channel (not designated) communicating with aperture 716 and serving to enable a surgeon to slip thread 726 into the aperture and to prevent the thread from slipping out of the aperture back through the access channel. The free end of thread 726 is also locked to body member 714 because projections 728 are too large, at their wide ends, to pass back through aperture 716. A loop 724 connected to body member 714 and the free end of thread 726 extending

9

beyond body member 714 are severed near body member 714.

The attachment of suture device 510 to an open blood vessel 36 or other tubular duct is schematically shown in FIGS. 8A through 8D. The open end of vessel 36 is first clamped by a hemostat 38 or other surgical instrument. Upon a placement of device 510 proximately to vessel 36, as illustrated in FIG. 8A, the free end of thread 526 is passed around the vessel. As shown in FIG. 8B, the free end of thread 526 is then passed through through loop 524. As the loop consequently formed by thread 526 is closed about blood vessel 36, care being taken to ensure the proper disposition of the loop about the end of the vessel, thread 526 is slipped through open finger or passageway 520 into bore 516. With the surgeon holding suture device 510 in place, as schematically indicated in FIG. 8C, thread 526 is pulled longitudinally through bore 516 until the loop formed by the thread has tightened sufficiently to close off and clamp blood vessel 36. As described above, serrations 528 function to prevent thread 526 from slipping back through bore 516 and to thereby lock the suture device around blood vessel 36. Upon the completion of the loop tightening operation, thread 526, as well as thread 524, is severed at a point near body member 514, as shown in FIG. 8D. Hemostat 38 may then be removed from the end of the clamped vessel.

The use of suture device 510 to close an open cut 42 is schematically depicted in FIGS. 9A through 9D. Upon a placement of device 510 proximately to body tissues 40 near cut 42, as illustrated in FIG. 9A, the free end of thread 526 is passed through tissues 40, cut 42 and tissues 44 on the other side of the cut. To facilitate this sewing operation, the free end of thread 526 is provided with a relatively inflexible extension 132 in the form of a hook-shaped needle 532. As shown in FIG. 9B, needle extension 532 is removed or cut from thread 526 upon the passage of the thread through tissue portion 44. Subsequently, the free end of thread 526 is passed through loop 524, as shown in FIG. 9C. As a loop consequently formed by thread 526 is closed, thereby drawing tissue portions 40 and 44 towards one another to close cut 42, thread 526 is slipped through open finger or passageway 520 into bore 516. Thread 526 is then pulled longitudinally through bore 516 until the loop formed by thread 526 has tightened to close cut 42 and clamp tissue portions 40 and 42 to one another. As described above, serrations 528 function to prevent thread 526 from slipping back through bore 516 and lock the suture device in a clamping configuration to the body tissues. Upon the tightening of thread 526, that thread, as well as thread 524, is severed at a point near body member 514, as shown in FIG. 9D.

It is to be noted that protuberances 511 and 513 have been omitted from FIGS. 8A-8D and 9A-9D for purposes of simplifying the drawing. In addition, FIGS. 9A-9C show surgical device 510 with an extension 530 on loop 524. Thread 530 serves to facilitate the handling of loop 524 in cases where loop 524 is too small to conveniently manipulate while passing thread 526 there-through. It is to be further understood that any of the particular embodiments of a suture device described herein may be used in performing the surgical operations described with reference to FIGS. 8A-8D and 9A-9D above.

As illustrated in FIG. 10, a suture device 810 comprises a thread member 826, a loop member 824, a connector element or joint portion 814, and inwardly projecting

10

aperture forming wings 817 and 818 on loop member 824. The suture device further comprises a locking mechanism in the form of a pair of inwardly projecting resilient protuberances 811 and 813 on wings 817 and 818. Thread member 826 is formed along a portion of its length with a series of conically tapering projections 828 and has an outer diameter OD1 defined by a maximum outer transverse dimension of projections 828. Projections 828 each taper from the maximum outer transverse dimension on a side facing joint portion 814 to a minimum transverse dimension at the adjacent projection.

Loop member 824 defines an opening 815 having an effective linear dimension or overall diameter OD2 (when the loop is circularly arranged) substantially larger than outer diameter OD1 of thread member 826. Connector or joint portion 814 serves to couple one end of thread member 826 to loop member 824. Loop member 824 with inwardly projecting wings 817 and 818, connector 814 and protuberances 811 and 813 define a generally oval aperture 816 having a linear dimension or size smaller than outer diameter OD1 of thread member 826. Generally, aperture 816 has an area smaller than the cross-sectional area of projections 828 at the large ends thereof.

Linear dimension or overall diameter OD2 of loop member opening 815 is at least twice as large as outer diameter OD1 of thread member 826. Concomitantly, opening 815 of loop member 824 has an area at least four times the cross-sectional area subtended by projections 828 at their largest width or diameter. This substantial difference in the dimensions of opening 815 and thread member 826 enables practical use of the suture. If opening 815 were smaller, relative to the outer diameter OD1 of thread member 826, than contemplated by the invention, the suture could not perform satisfactorily in surgical applications, inasmuch as the suture is very small. Moreover, during surgical operations surgeons wear gloves which interfere with facile manipulation of thread member 826 and loop member 824 and thus with the threading of the thread member through the loop member. The greater size of opening 815 facilitates a threading operation which otherwise could not be performed at all or could be performed only with the greatest difficulty.

In contrast to loop member opening 815 of suture device 110, loop member opening 815 of suture device 810 has a narrow range of operative sizes. This limitation arises from the fact that loop 824 is not severed during the surgical operation but instead remains an integral part of the suture after surgery has been completed. For example, if suture device 810 is used to close a tubular body organ such as a blood vessel or bile duct, the circumference of loop member 824 cannot exceed twice the circumference of the vessel or duct.

Protuberances 811 and 813 define a passageway or access channel 820 between opening 815 and aperture 816. The protuberances serve to prevent a removal of thread member 826 from aperture 816 upon a passing of thread member 826 through opening 815 (i.e., through loop member 824) and a subsequent pulling of thread member 826 into aperture 816 from opening 815 through access channel 820.

In using a suture in accordance with the embodiment of FIG. 10, thread member 826 is looped about a tubular member or is threaded through tissues to be stitched. The thread member is then passed through loop opening 815 and pulled through access channel 820 into

aperture 816. Upon a sufficient tightening of the loop formed by thread member 826, the free end of the thread member may be severed. In contrast to loop members 124 and 224 sutures 110 and 210 (FIGS. 1 and 2), respectively, the loop member 824 of suture 810 is not severed at the end of a stitching or ligating operation.

FIGS. 11-13 illustrate a suture 910 with collapsible hollow conical projections 928 similar to projections 228 of suture device 210 (FIG. 2), except that projections 928 have an internal structure which biases them into the closed configuration (FIG. 11). However, when acted upon by a force exerted along a thread member 926 in a direction away from a loop member 924, projections 928 open or expand, as indicated at 929 in FIG. 12. During use of suture 910 in ligating a tubular body organ 930, as shown in FIG. 13, only a single projection 931 is opened or expanded. The other projections 928 remain in a closed configuration, whereby thread 928 presents a smooth surface to contiguous body tissues. Of course, the thread construction of FIGS. 11-13 may be used in the all of the particular suture embodiments described above.

The suture devices described herein are all integrally molded pursuant to techniques well known in the art. The sutures are made of polyethylene, polypropylene, nylon, tetrafluoroethylene or other synthetic resin or polymeric material which is essentially inert and therefore biochemically safe for sustained contact with the body tissues of human beings and other animals. The suture needles are attached to the free ends of the thread members by embedding techniques also well known in the art.

Suture devices in accordance with the present invention can be used controlling bleeding vessels, tying off open ducts (e.g., bile ducts), creating anastomoses (connecting the open ends of two tubular sections in a splicing type operation), and suturing together flaps of skin or other body tissues on opposite sides of a cut. Suture devices as described herein, if appropriately dimensioned, can be used in microsurgery and neurosurgery and for such larger scale operations as binding sternums and approximating ribs.

It is to be noted that loop members of the various specific suture devices disclosed herein, for example, loop members 124 and 824 are made of a flexible, thin, thread-like element. In the case of suture device 110, the thin thread-like element facilitates severing of loop member 124 at the end of a suturing operation. In the case of suture device 810, the thin thread-like element enables loop member 824 to be wound about a body tissue such as a blood vessel or duct. Thus, the flexibility of loop member 824 enables suture device 810 to conform to the body tissues to which it is attached.

Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are preferred by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A suture device comprising:

a thread member provided along at least a portion of its length with a series of projections, said thread

member having an outer diameter defined by said projections;

a loop member defining an opening having a linear dimension substantially larger than said outer diameter, said loop member being formed by a flexible thread member;

joining means for connecting one end of said thread member to said loop member, at least one of said joining means and said loop member defining at least in part an aperture having a linear dimension smaller than said outer diameter, said aperture communicating with said opening defined by said loop; and

locking means, provided on at least one of said joining means and said loop member, for preventing a removal of said thread member from said aperture upon a passing of said thread member through said loop member and a subsequent pulling of said thread member into said aperture from said loop member.

2. The suture device set forth in claim 1 wherein said locking means includes at least one protuberance on said loop.

3. The suture device set forth in claim 2 wherein said protuberance projects towards said aperture.

4. The suture device set forth in claim 3 wherein said protuberance is undercut on a side facing said aperture.

5. The suture device set forth in claim 1 wherein said locking means includes two protuberances projecting from said loop towards said aperture.

6. The suture device set forth in claim 5 wherein said protuberances are undercut on a side facing said aperture.

7. The suture device set forth in claim 1 wherein said joining means comprises a Y-shaped connector piece between said one end of said thread member and said loop member.

8. The suture device set forth in claim 1 wherein said loop member is provided on a side opposite said joining means and said thread member with an additional member extending away from said loop member.

9. The suture device set forth in claim 1 wherein said extension takes the form of an additional thread member.

10. The suture device set forth in claim 1 wherein said aperture is generally triangular.

11. The suture device set forth in claim 1, further comprising a needle element attached to said thread member at an end thereof opposite said joining means.

12. The suture device set forth in claim 1 wherein said aperture is disposed at an end of said loop member opposite said joining means.

13. The suture device set forth in claim 1 wherein said aperture is disposed at the same side of said loop as said joining means.

14. A suture device comprising:

a thread member provided along at least a portion of its length with a series of projections, said thread member having an outer diameter defined by said projections;

a loop member defining an opening having a linear dimension substantially larger than said outer diameter, said loop member being formed by a flexible thread; and

a body member defining an aperture having a linear dimension smaller than said outer diameter, one end of said thread member being connected to one side of said body member, said loop member being

5,123,913

13

connected to another side of said body member substantially opposite said one side, said body member being provided with an access channel extending between said loop member and said aperture, said body member being further provided with locking means for preventing a removal of said thread member from said aperture upon a threading of said thread member through said loop member and a subsequent pulling of said thread member through said access channel into said aperture from said loop member.

15. A suture device comprising:

a thread member provided along at least a portion of its length with a series of projections, said thread member having an outer diameter defined by said projections;

a loop member defining an opening having a linear dimension at least two times as large as said outer diameter, said loop member being formed by a flexible thread;

joining means for connecting one end of said thread member to said loop member;

aperture forming means on said loop member along a portion thereof spaced from said joining means for defining an aperture having a linear dimension smaller than said outer diameter, said aperture communicating with said opening defined by said loop; and

locking means for preventing a removal of said thread member from said aperture upon a passing of said thread member through said loop member and a subsequent pulling of said thread member into said aperture from said loop member.

16. The suture device set forth in claim 15 wherein said locking means includes at least one protuberance on said loop.

17. The suture device set forth in claim 15 wherein said locking means includes two protuberances.

18. The suture device set forth in claim 17 wherein said protuberances are undercut on a side facing said aperture.

19. The suture device set forth in claim 15 wherein said projections are tapered from a larger transverse dimension down towards an end of said thread member opposite said joining means.

20. The suture device set forth in claim 15 wherein said thread member, said loop member, said joining means and said locking means are integrally molded.

21. The suture device set forth in claim 16 wherein said protuberance projects generally away from said joining means towards said aperture.

22. The suture device set forth in claim 21 wherein said protuberance is undercut on a side facing said aperture.

23. The suture device set forth in claim 16 wherein said protuberance is an integrally formed part of said aperture forming means.

24. A suture device comprising:

a thread member provided along at least a portion of its length with a series of resiliently collapsible

14

projections, said thread member having an outer diameter defined by said projections;

a loop member defining an opening having a linear dimension substantially larger than said outer diameter, said loop member being formed by a flexible thread;

joining means for connecting one end of said thread member to said loop member, at least one of said joining means and said loop member defining at least in part an aperture having a linear dimension smaller than said outer diameter, said aperture communicating with said opening defined by said loop; and

locking means, provided on at least one of said joining means and said loop member, for preventing a removal of said thread member from said aperture upon a passing of said thread member through said loop member and a subsequent pulling of said thread member into said aperture from said loop member.

25. The suture device set forth in claim 20 wherein said projections are collapsible under force applied along said thread member in one direction and expandable under force applied along said thread member in an opposite direction.

26. The suture device set forth in claim 25 wherein said projections are substantially hollow conical elements.

27. A suture device comprising:

a thread member provided along at least a portion of its length with a series of resilient projections having an internal structure biasing said projections into a collapsed configuration, said projections being expandable from said collapsed configuration into an opened configuration upon application of a force directed longitudinally in one direction along said thread member, said thread member having an outer diameter defined by said projections in said opened configuration;

a loop member defining an opening having a linear dimension substantially larger than said outer diameter;

joining means for connecting one end of said thread member to said loop member, at least one of said joining means and said loop member defining at least in part an aperture having a linear dimension smaller than said outer diameter, said aperture communicating with said opening defined by said loop; and

locking means, provided on at least one of said joining means and said loop member, for cooperating with a projection on said thread member to prevent a removal of said thread member from said aperture upon a passing of said thread member through said loop member and a subsequent pulling of said thread member into said aperture from said loop member.

28. The suture device set forth in claim 27 wherein said projections are substantially hollow conical elements.

* * * * *

EXHIBIT 14

CE 0086

FiberWire™

IMPORTANT PRODUCT INFORMATION WICHTIGE PRODUKTINFORMATION NOTICE D'UTILISATION IMPORTANTE IMPORTANTI INFORMAZIONI PER L'USO INSTRUCCIONES IMPORTANTES PARA EL USO



Manufacturer:
Arthrex Inc.
Naples, Florida 34108-1945 • USA
Tel-Free: +1 800 934-4404
www.arthrex.com

E. C. Representative:
Arthrex Med. Inst. GmbH
85757 Karlsruhe
Germany

Tel: +49 81 31 59 57 0 • Fax: +49 81 31 59 57 63 1



DF-0005
Rev. 6

ENGLISH

Description:

Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The Arthrex FiberWire may also be sold with needles attached (swaged) to the ends in a variety of sizes. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue. The Arthrex FiberWire is available non-dyed (white) or dyed and meets or exceeds U.S.P. and European standards (except for diameter).

Indications:

Arthrex FiberWire is indicated for use in soft tissue approximation and/or ligation. FiberWire is not for use in cardiac indications.

Actions:

Arthrex FiberWire, when tested per ISO/DIS 10933, Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Sensitization, had no reactions of allergic or sensitive nature. The dyed suture and coating are pharmacologically inactive.

Arthrex FiberWire is not absorbed, but may become encapsulated in the surrounding connective tissues. The Arthrex FiberWire is not known to have significant change in tensile strength *in vivo*.

Contraindications:

None known

Warnings:

Do not re-sterilize. Once open, discard unused suture. Do not expose to heat.

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Arthrex FiberWire for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with soft tissues, such as those found in the urinary or biliary tracts, may result in calculi formations. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions:

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Assure that all knots have been secured using accepted surgical knot-tying techniques. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Care should be taken to prevent damage to surrounding

tissue or use puncture due to improper handling of the needlepoint.

Do not grasp the needle at the point or swage, to avoid damage to these areas. Reapplying needles may cause them to lose strength and be less resistant to bending and breaking. Discard used needles in "sharp" containers.

Adverse Reactions:

Adverse reactions have not been noted with the Arthrex FiberWire product in animal testing. Common non-absorbable suture reactions may include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with soft solutions indirectly, minimal acute inflammatory tissue reaction, pain, edema, and erythema at the wound site. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Sterilization:

Arthrex FiberWire suture is supplied sterile. Method of sterilization: EO. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

Storage Conditions:

Store below 25°C, away from moisture and direct heat. Do not use after expiration date.

How Supplied:

The Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The suture is supplied sterile in pre-cut lengths and in some cases with swaged needles. The Arthrex FiberWire is available in non-dyed (white) or dyed colors. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue.

SYMBOLS USED ON LABELING

	Do not reuse		Quantity
	Suture unless the package is damaged or open. Method of sterilization: EO		See package insert
	Lot number		Use by year & month

DEUTSCH

Beschreibung:

Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Arthrex FiberWire ist unter Umständen auch mit an den Fadenenden befestigten (geswagten) Nadeln in unterschiedlichen Größen erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen- und Polyesterfasern. Die Beschichtung fungiert als Fadenrutschhilfe und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe. Arthrex FiberWire ist ungefärbt (weiß) oder gefärbt erhältlich und entspricht oder übertrifft USP- und europäische Standards (mit Ausnahme des Durchmessers).

Anwendungsgebiete:

Arthrex FiberWire ist für Weichteilapproximation und/oder -ligation vorgesehen. FiberWire nicht für kardio-indikationen verwenden.

Funktionen:

Tests bei Arthrex FiberWire gemäß ISO/DIS 10933, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Sensitization, ergaben keine allergischen oder empfindlichen Reaktionen. Das gefärbte Nahtmaterial und die Beschichtung sind pharmakologisch inaktiv.

Arthrex FiberWire wird zwar nicht absorbiert, jedoch unter Umständen vom umgebenden Bindegewebe eingekapselt. Bei Arthrex FiberWire wurde in vorläufigen Studien keine Veränderung der Reißfestigkeit festgestellt.

Gegenanzeigen:

Unbekannt

Warnhinweise:

Nicht resterilisieren. Unbenutztes Fadennahtmaterial nach dem Öffnen entsorgen. Von Hitze fernhalten.

Benutzer sollten vor dem Verschieben von Wunden mit Arthrex FiberWire mit den chirurgischen Prozeduren und Techniken vertraut sein, bei denen nicht-absorbierbare Fäden verwendet werden, da das Risiko einer Wundheilungsstörung mit der Anwendung von Arthrex FiberWire variiert. Das Nahtmaterial ist für die Anwendung in der Chirurgie geeignet.

Wie bei Fremdkörpern aller Art kann der längere Kontakt dieses oder jedes anderen Fadennahtmaterials mit Schleimhäuten (wie z.B. im Harn- und Gallenweg) vorhanden sind zu Calculusbildung führen. Bei der Drainage und beim Schließen von Infektionen oder kontaminierten Wunden sind die in der Chirurgie üblichen Praktiken zu beachten.

Vorichtsmaßnahmen:

Bei der Handhabung dieses oder jedes anderen Fadennahtmaterials sorgfältig darauf achten, dass das Material nicht beschädigt wird. Schließen durch Zusammenpressen oder Abkneten mit chirurgischen Instrumenten wie Zangen oder Nadeln ist nicht möglich. Vermeiden.

Sicherstellen, dass sämtliche Knoten gemäß den akzeptierten chirurgischen Knotenbildungstechniken sicher befestigt wurden. Voraussetzung für angemessene Wundheilung ist die Verwendung von zusätzlichen Knoten. Die Verwendung von zusätzlichen Knoten kann bei der Drainage von Infektionen und Entzündung des Gewebes durch das Nahtmaterial zu Vermeidung.

Chirurgien. Besonders beim Verketten von monofilen Fäden sind unter Umständen zusätzliche Verkettenungen angebracht. Sorgfältig vorgehen, um Schäden an umgebenden Gewebe und Benutzereinführung durch falsche Handhabung der Nadelspitze zu vermeiden.

Die Nadel nicht an der Spitze oder am Gesenk festhalten, um eine Beschädigung dieser Bereiche zu vermeiden. Nadeln können durch Überfahren an Stärke verlieren und gegen Verketten und Abkneten weniger widerstandsfähig werden. Nadeln in entsprechend gekennzeichneten Behältern entsorgen.

Nebenwirkungen:

Bei Tierversuchen wurden bei der Verwendung von Arthrex FiberWire keine Nebenwirkungen festgestellt. Zu den bei nicht-absorbierbarem Fadennahtmaterial beobachteten Reaktionen zählen unter Umständen Dehiscenz, Calculusbildung in Harn- und Gallenwegen bei längerem Kontakt mit Säuren (wie sie im Urin und in der Gallenflüssigkeit vorhanden sind), verstärkte Bakterieninfektion, minimale akute Gewebeschädigungen, Schmerzen, Ödem und Erythema an der Wundstelle. Vereinzelt können Stiche mit kontaminierten chirurgischen Nadeln kann zur Übertragung von Blutpathogenen führen.

Sterilisation:

Arthrex FiberWire wird steril geliefert. Sterilisationsmethode: EO. Nicht resterilisieren. Bei Beschädigung oder zu vor geöffneter Packung nicht verwenden. Offenes, unbenutztes Fadennahtmaterial entsorgen.

Lagerungsbedingungen:

Unter 25 °C trocknen und fern von direkter Hitzeinwirkung lagern. Nicht nach dem Verfallsdatum verwenden.

Lieferform:

Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Das Fadennahtmaterial wird steril in vorgeschrittenen Längen und in manchen Fällen mit geswagten Nadeln geliefert. Arthrex FiberWire ist ungefärbt (weiß) und gefärbt erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen- und Polyesterfasern. Die Beschichtung fungiert als Fadenrutschhilfe und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe.

AUF DER VERPACKUNG VERWENDETE SYMBOLE

	Nicht wiederverwenden		Quantität
	Steril, solange die Verpackung ungeschädigt und undurchdringt ist. Sterilisationsmethode: EO		See package insert
	Losnummer		Verfallsdatum

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Indications:
La suture Artrex FiberWire est indiquée pour la ligature et le rapprochement des tissus mous. La suture Artrex FiberWire n'est pas indiquée pour la chirurgie cardiaque.

Contre-indications:
Après réaction allergique ou sensible n'a été observée. La suture Artrex FiberWire est non résorbable. Elle peut cependant être encapsulée par le tissu conjonctif. Selon les données disponibles, la résistance à la traction de la suture Artrex FiberWire ne change pas de manière significative in vivo.

Précautions d'emploi:
Ne stériliser à nouveau. Jeter toute suture non utilisée dans l'emballage a été ouvert. Ne pas exposer à la chaleur.

Présentation:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et elle est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture est livrée stérile en différents longueurs préemballées. Elle est aussi disponible avec des aiguilles serres. La suture Artrex FiberWire est disponible en blanc (non teinté) ou en couleur (teinté). Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stériles et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus.

Conditions de stockage:
Conserver à une température maximale de 25°C et à l'abri de l'humidité comme des sources de chaleur directes. Ne pas utiliser après la date d'expiration.

Présentation:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et elle est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture est livrée stérile en différents longueurs préemballées. Elle est aussi disponible avec des aiguilles serres. La suture Artrex FiberWire est disponible en blanc (non teinté) ou en couleur (teinté). Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stériles et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus.

Précautions:
Ne stériliser à nouveau. Jeter toute suture non utilisée dans l'emballage a été ouvert. Ne pas exposer à la chaleur.

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Précaution:
La suture Artrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Descrizione:
FiberWire Artrex è disponibile in molte misure U.S.P. (le suture soddisfanno gli standard U.S.P. per suture, tranne il diametro). FiberWire Artrex può essere utilizzato anche con aghi di varie dimensioni attaccati (soddisfa anche). La suture consiste in maglie di fibre di polietilene e di poliestere tressate, sterilizzate e trattate in superficie per le applicazioni chirurgiche. Questo rivestimento gioca il ruolo di lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto. FiberWire Artrex è disponibile sia non tinta (bianco) che tinta e soddisfa o supera gli standard U.S.P. ed europei (non per diametro).

Indicazioni:
FiberWire Artrex è indicato per l'approssimazione e la legatura dei tessuti molli. FiberWire non va utilizzato in interventi cardiaci.

Controindicazioni:
Nessuna nota.

Avvertenze:
Non risterilizzare. Una volta aperta, gettare la sutura non utilizzata. Non esporre al calore.

Presentazione:
La sutura FiberWire Artrex esiste in diverse misure U.S.P. e viene fornita sterile in diversi pacchetti preimballati. È anche disponibile con aghi di varie dimensioni attaccati. La sutura FiberWire Artrex è disponibile in bianco (non tinta) o in colore (tinta). Questa sutura è composta da fibre di polietilene e da fibre di poliestere tressate, sterilizzate e trattate in superficie per le applicazioni chirurgiche. Questo rivestimento gioca il ruolo di lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto.

Condizioni di conservazione:
Conservare a una temperatura massima di 25°C e a lontananza da fonti dirette di calore. Non utilizzare dopo la data di scadenza.

Presentazione:
La sutura FiberWire Artrex esiste in diverse misure U.S.P. e viene fornita sterile in diversi pacchetti preimballati. È anche disponibile con aghi di varie dimensioni attaccati. La sutura FiberWire Artrex è disponibile in bianco (non tinta) o in colore (tinta). Questa sutura è composta da fibre di polietilene e da fibre di poliestere tressate, sterilizzate e trattate in superficie per le applicazioni chirurgiche. Questo rivestimento gioca il ruolo di lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto.

Precaution:
La sutura FiberWire Artrex existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Precaution:
La sutura FiberWire Artrex existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Artrex FiberWire est également commercialisée avec des aiguilles de différentes tailles. Cette suture se compose de fils de polyéthylène et de fibres de polyester tressées, chirurgicales. Ce roulement joue le rôle de lubrifiant pour faciliter le glissement du fil. Le serrage des nœuds est assuré du à la travers des tissus. La suture Artrex FiberWire est disponible en blanc (non teinté) ou teinté, et est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Descripción:
La sutura FiberWire de Artrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas de U.S.P. para suturas, excepto en el diámetro). También es posible encontrar la sutura FiberWire de Artrex en diversos tamaños con agujas incorporadas (también las hay). La sutura está hecha de mallas de polietileno y políester trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido. La sutura FiberWire de Artrex viene en modelos sin tinte (blanco) o teñida y cumple o supera las normas de U.S.P. y Europa (excepto en el diámetro).

Indicaciones:
La sutura FiberWire de Artrex está indicada para aplicaciones de aproximación y ligadura de tejidos blandos. La sutura FiberWire no está indicada para uso cardíaco.

Contraindicaciones:
Ninguna conocida.

Advertencias:
No esterilizar de nuevo. Una vez abierto el paquete, desechar la sutura no utilizada. No exponer al calor.

Presentación:
La sutura FiberWire de Artrex existe en varias medidas aprobadas por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en sobres de longitud predefinida y en algunos casos con agujas incorporadas. La sutura FiberWire de Artrex se encuentra disponible en modelos sin tinte (blanco) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25 °C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:
La sutura FiberWire de Artrex existe en varias medidas aprobadas por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en sobres de longitud predefinida y en algunos casos con agujas incorporadas. La sutura FiberWire de Artrex se encuentra disponible en modelos sin tinte (blanco) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

Precaution:
La sutura FiberWire de Artrex existe en varias medidas aprobadas por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en sobres de longitud predefinida y en algunos casos con agujas incorporadas. La sutura FiberWire de Artrex se encuentra disponible en modelos sin tinte (blanco) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

Precaution:
La sutura FiberWire de Artrex existe en varias medidas aprobadas por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en sobres de longitud predefinida y en algunos casos con agujas incorporadas. La sutura FiberWire de Artrex se encuentra disponible en modelos sin tinte (blanco) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

Precaution:
La sutura FiberWire de Artrex existe en varias medidas aprobadas por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en sobres de longitud predefinida y en algunos casos con agujas incorporadas. La sutura FiberWire de Artrex se encuentra disponible en modelos sin tinte (blanco) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

Reacciones adversas:
No se han detectado reacciones adversas del producto FiberWire de Artrex en pruebas con animales. Entre las reacciones comunes de las suturas no absorbibles se encuentran: obstrucción de las heridas, formación de cicatrices en los tejidos blandos y bilar en condiciones de contacto prolongado con soluciones salinas tales como la citina y la bala, mayor propensión a infecciones bacterianas, reacción mínima inflamatoria aguda del tejido, dolor, edema y entena en el sitio de la herida. El pinchazo accidental con agujas quirúrgicas usadas podría causar la transmisión de patógenos a través de la sangre.

Estérilización:
La sutura FiberWire de Artrex se suministra estéril. Método de esterilización - EO.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25 °C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:
La sutura FiberWire de Artrex existe en varias medidas aprobadas por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en sobres de longitud predefinida y en algunos casos con agujas incorporadas. La sutura FiberWire de Artrex se encuentra disponible en modelos sin tinte (blanco) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25 °C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:
La sutura FiberWire de Artrex existe en varias medidas aprobadas por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en sobres de longitud predefinida y en algunos casos con agujas incorporadas. La sutura FiberWire de Artrex se encuentra disponible en modelos sin tinte (blanco) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25 °C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:
La sutura FiberWire de Artrex existe en varias medidas aprobadas por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en sobres de longitud predefinida y en algunos casos con agujas incorporadas. La sutura FiberWire de Artrex se encuentra disponible en modelos sin tinte (blanco) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25 °C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25 °C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

EXHIBIT 15



US005318575A

United States Patent [19][11] **Patent Number:** **5,318,575****Chesterfield et al.**[45] **Date of Patent:** **Jun. 7, 1994****[54] METHOD OF USING A SURGICAL REPAIR SUTURE PRODUCT****[75] Inventors:** **Michael P. Chesterfield**, Norwalk;
Ilya Koyfman, Orange, both of Conn.**[73] Assignee:** **United States Surgical Corporation**,
Norwalk, Conn.**[21] Appl. No.:** **829,423****[22] Filed:** **Feb. 3, 1992****[51] Int. Cl.:** **A61B 17/00****[52] U.S. Cl.:** **606/151; 606/228;**
606/231; 128/898; 623/13**[58] Field of Search:** **606/228, 231, 151;**
623/13; 128/898

4,557,264 12/1985 Hinsch .
 4,583,541 4/1986 Barry .
 4,620,542 11/1986 Menezes et al. .
 4,625,717 12/1986 Covitz .
 4,643,178 2/1987 Nastari et al. .
 4,655,769 4/1987 Zachariades .
 4,667,662 5/1987 Titone et al. .
 4,730,615 3/1988 Sutherland et al. .
 4,759,765 7/1988 Van Kampen 623/13
 4,790,850 12/1988 Dunn et al. 623/13
 4,792,336 12/1988 Hlavacek et al. .
 4,802,477 2/1989 Gabbay .
 4,813,416 3/1989 Pollak et al. .
 4,819,458 4/1989 Kavesh et al. .
 4,886,691 12/1989 Winckhofer .
 4,896,668 1/1990 Popoff et al. .

(List continued on next page.)

[56] References Cited**U.S. PATENT DOCUMENTS**

1,717,766 6/1929 Eimler .
 1,950,799 3/1934 Jones . .
 2,987,062 6/1961 Ellison .
 3,105,493 10/1963 Usher .
 3,111,945 11/1963 Von Solbrig .
 3,113,115 12/1963 Ziegler et al. .
 3,187,752 6/1965 Glick .
 3,359,983 12/1967 Northey .
 3,469,573 9/1969 Florio .
 3,473,528 10/1969 Mishkin et al. .
 3,565,077 2/1971 Glick .
 3,570,497 3/1971 Lemole .
 3,577,601 5/1971 Mariani et al. .
 3,802,438 4/1974 Wolvek .
 4,014,973 3/1977 Thompson .
 4,037,603 7/1977 Wendorff .
 4,043,344 8/1977 Landi et al. .
 4,047,533 9/1977 Perciaccante et al. .
 4,119,091 10/1978 Partridge .
 4,137,394 1/1979 Meihuizen et al. .
 4,201,215 5/1980 Crossett et al. .
 4,263,904 4/1981 Judet .
 4,279,248 7/1981 Gabbay .
 4,356,138 10/1982 Kavesh et al. .
 4,403,012 9/1983 Harpell et al. .
 4,413,110 11/1983 Kavesh et al. .
 4,455,273 6/1984 Harpell et al. .
 4,512,346 4/1985 Lemole .
 4,520,822 6/1985 Menezes et al. .
 4,535,764 8/1985 Ebert .

FOREIGN PATENT DOCUMENTS

2730571 of 0000 Fed. Rep. of Germany .
 3042699 of 0000 Fed. Rep. of Germany .
 3244680 of 0000 Fed. Rep. of Germany .

OTHER PUBLICATIONS

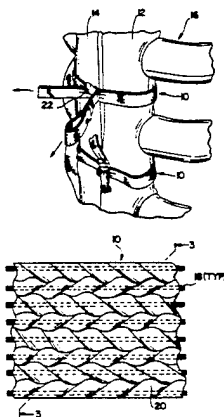
Sirivella, et al., "Improved Technique for Closure of Medium Sternotomy Incision/Mersilene [Ethicon, Inc.] Tapes Versus Standard Wire Closure" J. Thorac. Cardiovasc. Surg., 1987; 94:591-5.

(List continued on next page.)

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—J. A. Schmidt

[57] ABSTRACT

Textile surgical articles are disclosed which are constructed in whole or in part from high tenacity low elongation fibers such as ultra-high molecular weight extended chain polyethylene high tenacity fibers. The products may be braided, woven or knitted, such as braided tapes, hollow braids and spiroid braids. The high tenacity low elongation fibers provide structures having greatly increased strength and decreased elongation, a combination of properties which is uniquely applicable and superior for repairing body tissue. The products may be plasma treated to reduce slip.

12 Claims, 2 Drawing Sheets

5,318,575

Page 2

U.S. PATENT DOCUMENTS

4,916,193 4/1990 Tang et al. 606/231
 4,920,959 5/1990 Witzel et al. .
 4,942,875 7/1990 Hlavacek et al. .
 4,943,292 7/1990 Foux .
 4,944,753 7/1990 Burgess et al. .
 4,944,974 7/1990 Zachariades .
 4,955,913 9/1990 Robinson .
 4,959,069 9/1990 Brennan et al. .
 4,976,257 12/1990 Akin et al. .
 4,987,665 1/1991 Dumican et al. .
 5,002,574 3/1991 May et al. 623/13
 5,024,618 6/1991 Tepic .
 5,059,213 10/1991 Chesterfield et al. .

OTHER PUBLICATIONS

Product brochure for Deknatel Inc. (Pfizer) Dekna—
 Band sternotomy closure system.

Miller et al., "Repair of Sternal Dehiscence Using a
 Harrington Compression System", Ann. Thorac. Surg.,
 45:684-685, Jun. 1988.

Product Brochure for Pilling (Fort Washington Pa.
 Sternal Approximation and Fixation System.

Mulch et al., "Closure of Longitudinal Sternotomy with
 Absorbable Sutures", Thorac. Cardiovasc. Surgeon, 34,
 191-193 (1986).

Johnston, Jr. et al., Mersilene [Ethicon, Inc.] "Ribbon
 Closure of the Median Sternotomy: An Improvement

Over Wire Closure" (1984) and Mersilene Product Lit-
 erature.

Labitzke et al., "'Sleeve-Rope Closure' of the Median
 Sternotomy After Open Heart Operations", Thorac.
 Cardiovasc. Surgeon, 31, 127-128 (1983), pp. 127-128.
 Kalush et al., "Peristernal Closure of Median Sternot-
 omy Using Stainless Steel Bands" (1975), pp. 172-173.
 Timmes et al., "A New Method of Sternal Approxima-
 tion", Ann. Thorac. Surg., vol. 16, No. 5, May, 1973,
 pp. 544-546 [the Wolvek approximator].

Sanfelippo et al., "Nylon Bands for Closure of Median
 Sternotomy Incisions/An Unacceptable Method", Ann.
 Thorac. Surg., vol. 13, No. 4, Apr., 1972, pp. 404-406.
 LeVeen et al., "Nylon-Band Chest Closure", Arch.
 Surg., vol. 96, Jan. 1968, pp. 36-39.

Goodman et al., "Technique of Closure of Median Ster-
 notomy with Transternal Figure-of-Eight Wires", J.
 Cardiovasc., Surg., vol. 27, 1986, pp. 512-513.

Vincent, "Update on Sternal Osteosynthesis", Ann.
 Thorac. Surg., vol. 41, Feb. 1986, pp. 216-218.

Vincent, "Controlled Tension Osteosynthesis A Way
 To Prevent Or Cure The Cardiac Sternotomy Com-
 plicators".

Allied Signal Inc.'s Product brochure for SPECTRA
 extended chain polyethylene fibers.

FIG. 1

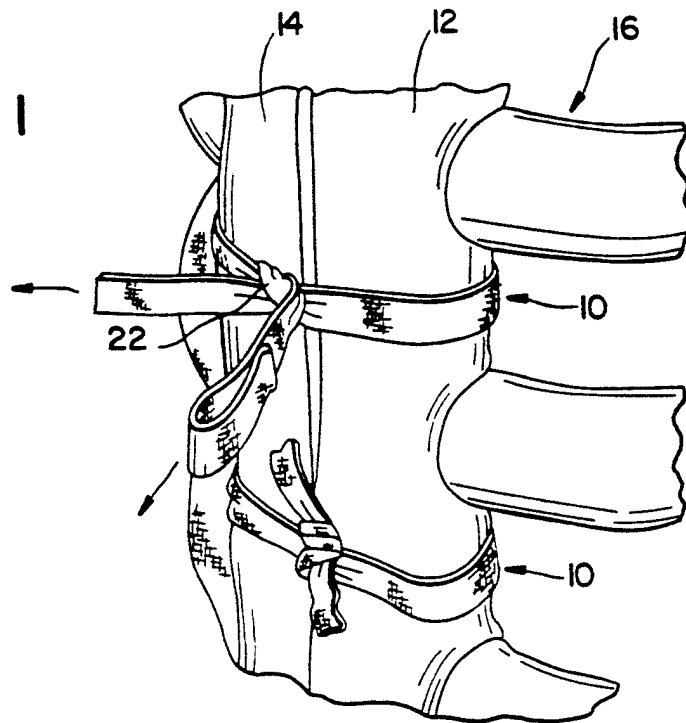


FIG. 2

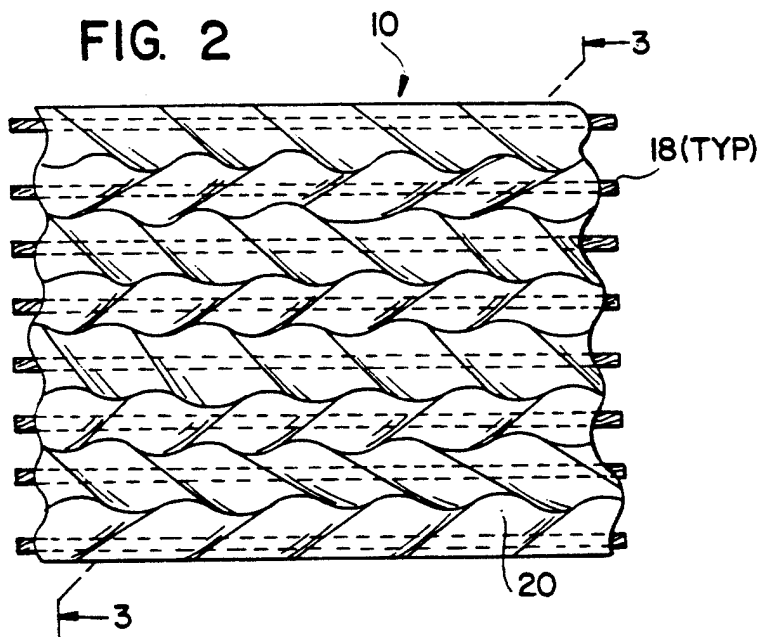
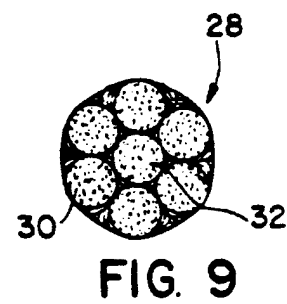
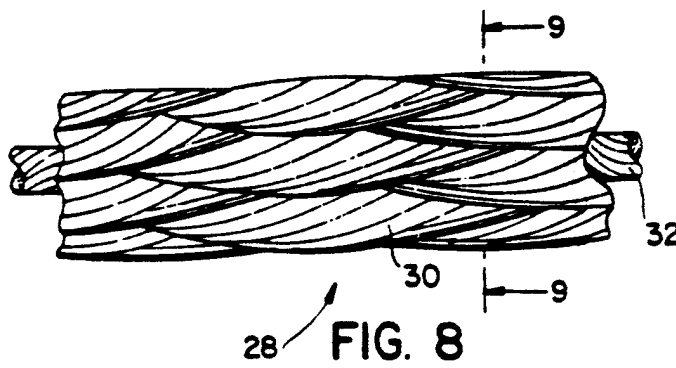
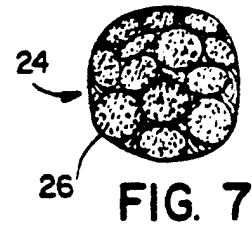
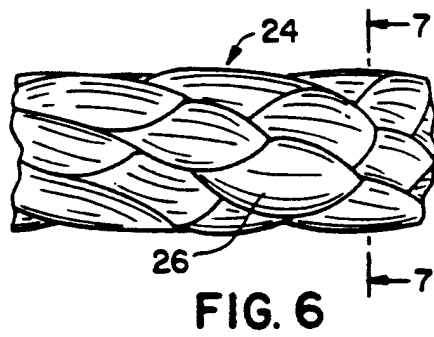
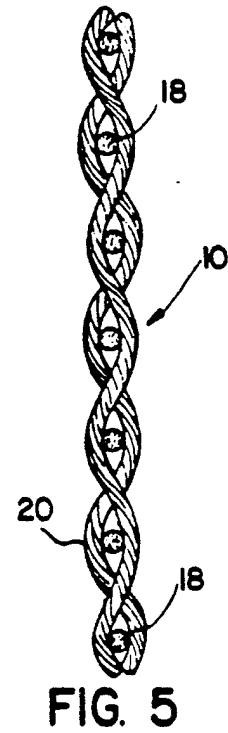
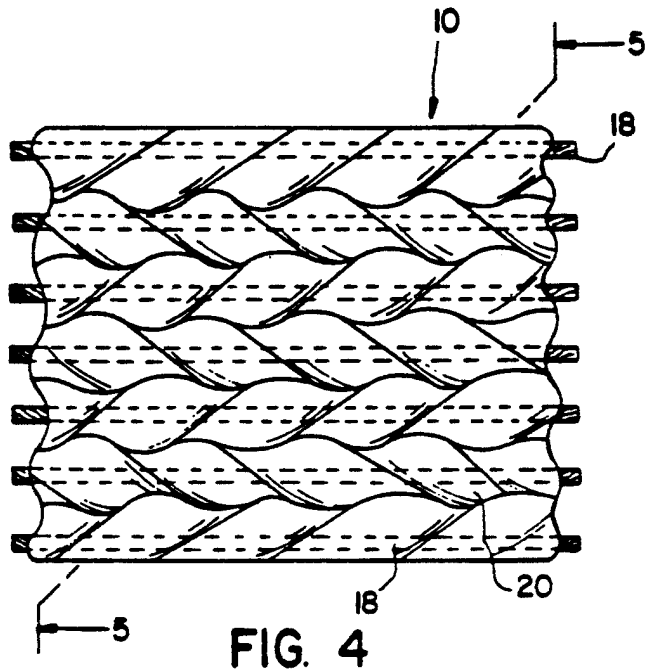


FIG. 3





METHOD OF USING A SURGICAL REPAIR SUTURE PRODUCT

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to suture products for surgical repair of body tissue. In particular, the invention is directed to reinforced surgical repair products for repairing the human sternum after surgery.

2. Background of the Prior Art

Presently there are many known products for repairing human body tissue in areas where a repair may be required either as a result of an injury or during or after surgery. In particular, it is well known to utilize suture products in the form of elongated strands to repair human body tissue as well as utilizing two-part fasteners or metal staples for attaching body tissue after portions have been removed during surgery.

For example, sutures intended for repairing soft body tissue are usually constructed of a plurality of filaments and applied to the tissue with any number of surgical needles. More recently, a certain amount of emphasis has been placed upon repairing surgical bone utilizing an elongated surgical product either in the form of a flat band or in the form of a strand having the construction similar to a suture by simply utilizing a needle to penetrate the bone to apply the repair product to the bone in a manner which physically retains the separated bone portions together to promote permanent healing. One such example is disclosed in U.S. Pat. No. 4,535,764 to Ebert which relates to a surgical bone tie having a needle connected to one end of a band such that the band may be looped and arranged to be appropriately looped around the bone portions requiring repair.

U.S. Pat. No. 4,813,416 relates to a band assembly and method for sternum closing with which the sternum halves are brought to abutting closure utilizing a band having a needle at one end to facilitate looping the band in position to retain the sternum portions in adjacent butting contacting relation.

Numerous other products have been used to retain bone portions together to promote healing while numerous suture products have been used to retain soft tissue to retain healing.

While many attempts have been made to provide such products little emphasis has been applied to the physical strength characteristics of the components which form the actual suture or band product in order to provide the surgeon with precision control on the product. Moreover, control is required on the tissue to which the product is applied in a manner which will promote healing of the tissue, yet will not cause unnecessary cutting of the tissue when force is applied to the product and the force is in turn applied to the tissue.

A particularly desirable product for accomplishing these goals would preferably display substantial strength without significant elongation to facilitate retaining the tissue portions together. In the case of attaching separate bone portions of the sternum together after open heart surgery for example, it has been necessary to utilize metal wire filaments by looping the wire filaments around the sternum portions and actually twisting the filament ends together to form an attachment. The metal wire displayed sufficient strength to retain the bone portions together without elongation. However, the wire represented a relatively sharp non-absorbable foreign body which remains embedded

within the body tissue and thus presents a potential source of infection or other complications as a result of its presence within the body. Moreover, the relatively sharp characteristics of the wire present a danger of cutting into the bone during the application to the sternum. The sharp wire also presents a hazard to the surgeon and operating room personnel in that the wire may penetrate surgical gloves and cut the surgeon or attendant personnel, thereby creating a potential site for transmission of disease.

While utilization of wire sutures has been used and accepted during open heart surgery there remains room for improvement in the products used for strapping the split sternum portions together. Desirably, it would be best to provide a known metallic product which not only provides the strength to elongation characteristics of the metal sutures but which may be utilized to form a tying product for soft as well as hard tissue, in a manner which will minimize the dangers of cutting of the tissue in the surrounding areas. The present invention is directed to such a product.

SUMMARY OF THE INVENTION

In accordance with the present invention, textile surgical articles are disclosed which are made in whole or in part from high tenacity low elongation fibers such as ultra high molecular weight extended chain polyethylene high tenacity fibers. One such fiber is Spectra yarn from Allied Signal Corp. The products may be braided, woven or knitted, although braided tape, hollow braids and spiroid braids are preferred. The high tenacity low elongation fibers provide structures having greatly increased strength and decreased elongation.

In one embodiment, braided tapes are made from Spectra yarn. In an alternative embodiment braided tapes are made with Spectra runners and bioabsorbable, Dacron polyester and/or nylon fill yarns.

Further alternative embodiments include tubular braided structures having a core made in whole or in part from high tenacity low elongation fibers or spiroid braided structures made in whole or in part from high tenacity low elongation fibers.

In a preferred method of the invention, a braided tape reinforced with ultra-high molecular weight high tenacity fibers is used to join a divided sternum by tying, or other appropriate means. The tape has a very high strength, preferably equal to or greater than 35 kg. straight pull and more preferably greater than about 50 kg. straight pull, and low elongation at break, preferably below about 20%, more preferably below about 10 to 15%, and most preferably below about 5%.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described hereinbelow wherein:

FIG. 1 is a perspective view of a portion of a split human sternum illustrating one application of the present invention for retaining the split portions together to promote healing;

FIG. 2 is an enlarged view of the suture product shown in FIG. 1 illustrating one embodiment wherein the elongated product is a flat braided member and contains at least eight reinforcing filaments extending along the length;

FIG. 3 is a cross-sectional view taken along lines 3—3 of FIG. 2;

3

FIG. 4 is an enlarged view of an alternative embodiment of the suture repair product of FIG. 2 wherein the elongated braided product contains at least seven reinforcing filaments extending along the length;

FIG. 5 is a cross-sectional view taken along lines 5—5 of FIG. 4;

FIG. 6 is a view of an alternative embodiment of the suture repair product wherein the elongated member is a spiroid braided member having a generally circular cross-section containing at least one elongated reinforcing member;

FIG. 7 is a cross-sectional view taken along lines 7—7 of FIG. 6;

FIG. 8 is a view of another alternative embodiment of the suture repair product wherein the elongated product is a hollow braided member having a generally circular cross-section and contains at least one elongated reinforcing member extending centrally thereof along the length; and

FIG. 9 is a cross-sectional view taken along lines 9—9 of FIG. 8.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to FIG. 1 there is illustrated a sternum closure ribbon 10 constructed according to the present invention and positioned to retain portions 12,14 of a human sternum 16 together. The band 10 is preferably a braided product as shown in FIGS. 2 and 4 having a plurality of elongated filamentary reinforcing members of ultra high molecular weight polyethylene fibers. The fibers may be plasma treated to reduce slip characteristics of the yarn, if desired. In particular, such fibers as extended chain polyethylene high tenacity fibers (ECPE) marketed under the trademark SPECTRA® by Allied-Signal Technologies, Petersburg, Va. 23804 are preferred as reinforcing members provided in the product of the present invention. SPECTRA 1000 yarn is suitable. These extended chain fibers exhibit a molecular weight generally between about 1 million to about 5 million but also may be as low as 500,000. They exhibit a very substantial degree of crystalline orientation (95–99%) and crystalline content (60–85%). As a result the fibers exhibit strengths from about 375 kpsi (thousands of pounds per square inch) to about 560 kpsi and tensile moduli of from about 15 msi (millions of pounds per square inch) to about 30 msi. The significant strength and stability of these fibers are caused by the high degree of molecular orientation. Moreover, since the fibers can be provided as multifilament or monofilament fibers which can be braided, woven, knitted or otherwise processed to form a textile product it will be readily appreciated that any number of reinforced textile products may be provided similar to the band 10 shown in the drawings, but with numerous alternative applications as will be described hereinbelow.

Referring now to FIG. 2, the band 10 shown in FIG. 1 is shown in greater detail as an elongated flat braided textile product having a plurality of high molecular weight fibers 18 extending along the length of the band.

The elongated fibers 18 are preferably made of ECPE marketed under the SPECTRA® trademark and are surrounded by braided fibers 20 which may be of the bioabsorbable type. For example, fibers 20 may be made of any suitable bioabsorbable polymeric material such as polymers or copolymers of glycolide, lactide, p-dioxanone, polyester, polyamino acids and the like as disclosed in U.S. Pat. Nos. 2,668,162; 3,297,033; 3,636,956;

4

3,736,646; and 3,839,297. The number of reinforcing filaments 18 included in the braided band 10 shown in FIG. 2 is optional as is the specific construction of the band. For example, as seen in FIG. 4, there is an example of an alternative braided band construction having seven reinforcing filaments 18 of high molecular weight, high strength fibers of the type shown in FIG. 2. Furthermore, as seen in FIG. 7, there is an alternative elongated embodiment of spiroid braided construction of generally circular cross-section and comprised of one or more elongated filaments 26 of high molecular weight, high strength, with the remainder of the braid being of bioabsorbable filamentary materials to form a braided rope-like construction of generally circular cross-sectional configuration as shown in FIG. 7. Alternatively the braided product 22 may be constructed entirely of such high molecular weight, high strength, elongated filaments 24. Braid constructions having a circular cross-section are described in U.S. Pat. Nos. 3,565,077 and 5,019,093. Any number of combinations of bioabsorbable yarns, filamentary or otherwise, and/or non-absorbable, and high strength filaments are contemplated, depending upon the intended application.

In FIGS. 8 and 9 there is shown a hollow braid construction 28 having a sheath constructed of bio-absorbable yarns 30 and having a core 32 of high molecular weight, high strength filament. Any number of alternative combinations of 0 to 100% absorbable filamentary or otherwise, and/or non-absorbable yarns and high strength filaments are contemplated depending upon the intended application.

It will be appreciated that in addition to the examples which follow hereinbelow, numerous alternative textile constructions may be incorporated into the present invention to form a reinforced band for attaching body tissue such as a soft tissue or bone tissue without suffering from the disadvantages from presently known materials. For example, it is conceivable within the scope of the present invention to provide a woven structure containing a plurality of elongated high strength filaments 18 in the warp direction wherein the filler yarns are of a suitable bioabsorbable material such as polymers or copolymers of glycolide, lactide, p-dioxanone, polyester, polyamino acids and the like, or with fill yarns of a nonabsorbable material such as Dacron polyester or nylon. Likewise, knitted structures may be strengthened by reinforcement with high tenacity fibers. It will be appreciated that in each of the embodiments discussed herein the strength characteristics of the high tenacity, low elongation fibers 18 will provide the substantial force carrying capability to the elongate product while the fibers 20 surrounding the high strength filaments will provide the necessary structural support to the main fibers for forming the product. The surrounding fibers will also define the "hand" or "feel" of the band.

Accordingly, it is possible in one application to position the reinforced structure 10 about the split portions 13,14 of the human sternum 16 as shown in FIG. 1 whereby substantial force may be applied to the band by tying the band either by a knot 22 shown in FIG. 1, or by other techniques whereby significant force may be applied and retained to promote natural healing of the sternum portions 12,14, e.g. mechanical connecting devices such as buckles, etc. See, for example, U.S. Pat. No. 4,813,416. It has been found that such a band has a strength to elongation ratio comparable to stainless

5

steel. The strength and load carrying capability of the elongated filaments 18 is sufficient to transmit substantial force to the sternum with minimum elongation occurring to the fibers thereby permitting the sternum portions to undergo a natural healing process. Furthermore, in addition to the textile processes of braiding and weaving it should be noted that alternative textile processes may be utilized including knitting techniques, provided that the final product contains a plurality of elongated high strength filaments 18,22 extending along at least the length of the product in the force-carrying direction to maintain the tissue portions together.

The braided product also may be made on a so-called spiroid braider by a method whereby a plurality of filament dispensers are moved in the same direction to different positions around a closed loop. In addition, the braid product may be produced by a conventional braiding process by directing a plurality of yarn dispensers along in equal and opposite undulating paths while directing the filaments or filler fibers toward a common braiding zone. In either process the final braided product will be manufactured to include a plurality of high strength, high molecular weight, high tenacity filaments as disclosed hereinabove, either as a component of the product, e.g. a core, or as the sole material used to construct the product. In addition, the yarn and/or product may be plasma treated depending upon the particular needs or intended application so as to reduce the perceived "slipperiness" of the product as desired.

For example, in any of the braided products disclosed herein the portions of the yarns may be of such high molecular weight, high tenacity filaments while the remaining portions are of absorbable or non-absorbable fibers or filaments. Further, the yarns may also be entirely of such high molecular weight, high tenacity filaments. For such products containing a core, the core may be as noted above, in combination with various types of fibers and/or filaments, absorbable or non-absorbable as described herein.

The final product could be provided with a surgical needle at one or both ends to facilitate insertion of the product into the body tissue whether the body tissue be soft skin tissue or hard bone tissue, or the needles may be utilized to facilitate looping the product into and out of spaces formed between the component members of the body such as the components forming the human sternum. Alternatively, the product could be provided with a needle at each end to facilitate ease of application to the body portions. In either event, the strength and the load carrying filaments 18 and the minimal elongation to strength percentage renders such filaments ideal for incorporation into a final product wherein body portions can be retained together to promote healing. In particular, the formation of a surgical suture repair product utilizing textile processes in combination with bioabsorbable filaments renders the incorporation of high tenacity, high strength, high molecular weight filaments 18 as an ideal combination to form a surgical suture repair product.

The following examples are provided for flat tapes and braids which can be utilized to tie two half portions of a human sternum to promote healing. In the examples which follow, all tapes or braids use Dacron polyester yarn. Braiding of the tapes or braids with Dacron yarns are noted for exemplary purposes only and such yarns may be appropriately substituted with any other suitable bioabsorbable or nonabsorbable yarns, as desired or

6

appropriate for a particular construction. Of course, substitution of different yarns may require variations to the structure as required to accommodate changes in density and/or fiber denier. The fibers may be twisted or air entangled periodically to create a false twist.

EXAMPLE 1

A braided tape of Spectra 1000 high tenacity polyethylene multifilament fibers (60 filaments, 215 denier) was made on a 15 carrier flat tape braider with 7 parallel runners. This structure is shown in FIGS. 4 and 5. Tests showed the following properties.

Denier =	10,585
Tape Thickness =	0.66 mm
Tape Width =	3.91 mm
Knot pull =	47.5 kg
Straight pull =	66.5 kg
Pick count =	20 crossovers per inch

The tape of this example was made with air entangled rather than twisted yarn. It is contemplated that the yarn could instead be twisted prior to braiding, with all or some of the yarn twisted in either the "s" or "z" directions. Twisted yarn should increase strength and decrease slipperiness of the tape.

EXAMPLE 2

A braided tape having multifilament Spectra 1000 runners (60 filaments, 215 denier) and Dacron fill yarns was made on a 17 carrier braider with 8 parallel runners. This structure is shown in FIGS. 2 and 3. The Dacron fill yarns were made with three plies of air entangled 100 denier, 54 filament Dacron type 55 yarn. The properties of the tape were measured as follows:

Denier =	7,551
Tape Thickness =	0.34 mm
Tape Width =	3.14 mm
Knot pull =	36.5 kg
Straight pull =	53.6 kg
Elongation at break =	3.4%
Pick count =	26 crossovers per inch

EXAMPLE 3

A braided tape is made with Spectra 1000 runners (60 filaments, 215 denier) and nylon fill yarn. The nylon fill yarn is made from three plies of 100 denier, 34 filament type 385 Dupont bright air entangled nylon yarns. The tape may be made to the desired width, thickness and pick count on any appropriate braider, such as a 15 carrier braider with 7 runners or a 17 carrier braider with 8 runners or a 21 carrier braider with 10 runners.

EXAMPLE 4

A braided tape is made with Spectra 1000 runners (60 filaments, 215 denier) and a bioabsorbable fill yarn such as a yarn made from a copolymer of glycolide and lactide. The bioabsorbable fill yarn may be twisted or air entangled and plied to a total denier of about 300 denier. The tape may be made to the desired width thickness and pick count on any appropriate braider, such as a 15 carrier braider with 7 runners or a 17 carrier braider with 8 runners or a 21 carrier braider with 10 runners.

5,318,575

7

EXAMPLE 5

A braided tape of plasma treated spectra 1000 high tenacity polyethylene multifilament fibers (60 filaments, 215 denier) was made on a 15 carrier flat tape braider with 7 parallel runners. Tests showed the following properties:

Denier =	5,338
Tape Thickness =	0.40 mm
Tape Width =	3.21 mm
Knot pull =	47.5 kg
Straight pull =	66.5 kg
Elongation at break =	8.6%
Pick count =	25 crossovers per inch

The tape of this example was made with air tangled rather than twisted yarn. It is contemplated that the yarn could instead be twisted prior to braiding, with all or some of the yarn twisted in each of the "s" or "z" directions.

The tape made from plasma treated yarn was perceptibly less slippery than the tape of Example 1, which may be desirable under some circumstances.

EXAMPLE 6

A suture of spiroid braid construction was made on a 15 carrier spiroid braider using Spectra 1000 yarn (60 filament, 215 denier). The braid is shown in FIGS. 6 and 7. The braid had the following properties.

Denier =	3,248
Diameter =	0.832 mm
Knot pull =	32.4 kg
Straight pull =	43.0 kg
Elongation at break =	14%

Spiroid sutures may be made with twisted yarn with a variety of carriers, such as 9, 12, 20 or 25 carriers, as desired to obtain a particular configuration.

EXAMPLE 7

A suture of hollow braid construction having a Spectra 1000 core was made, and is shown in FIGS. 8 and 9. Dacron air entangled bright polyester yarn (40 denier, 8 filament, type 55) was used on the carriers of an 8 carrier braider (4 carriers travelling in the S direction, 4 carriers travelling in the Z direction) to make a sheath surrounding a core of untwisted Spectra 1000 yarn. The properties of the suture were as follows.

Denier =	550
Diameter =	0.20 mm
Knot pull =	3.9 kg
Straight pull =	7.9 kg
Elongation at break =	3.3%

A wide variety of hollow braid constructions are contemplated. Thus, sutures having Spectra 1000 core or components can be made on braiders having 12, 16, 24, 28 or 32 carriers, and numerous yarns can be used to form a sheath surrounding the core, such as bioabsorbable yarn; Dupont Dacron polyester air entangled bright yarn (such as 100 denier, 54 filament type 55 bright yarn or 70 denier, 34 filament type 52 bright yarn); or Du-

8

pont air entangled nylon yarn (such as 40 denier, 13 filament type 335 bright yarn or 100 denier 34 filament type 385 bright yarn or 70 denier, 34 filament type 185 bright yarn or 55 denier 17 filament type 865 bright yarn, or 15 denier 7 filament type 180 bright yarn).

The core yarns may be twisted to condense the structure or plied to increase strength and denier. The sheath yarns may also be twisted, if desired.

In the foregoing examples, all physical tests were conducted at 73° F., 50% relative humidity on an Instron Corporation Model 4502 test apparatus. Knot pull tests were performed using a 6 inch gauge length with a 0.5 inch per minute crosshead speed. Straight pulls were made using a 10 inch gauge length with a 10 inch per minute crosshead speed. Yarn or tape grips were used, as appropriate.

While the foregoing description contains many specifics, it will be understood that numerous modifications may be made within the scope of the appended claims. By way of example, a wide variety of yarn substitutions may be made to arrive at various braided tape or hollow and spiroid suture configurations constructed in whole or in part from high tenacity reinforcing fibers. In addition, bioabsorbable and non-bioabsorbable yarns may be substituted as desired to achieve properties and characteristics suitable for a particular situation.

We claim:

1. A method for repairing split portions of body tissue comprising looping a flexible elongated member about the body tissue in a manner to attach the portions in adjacent engaged relation to promote natural healing thereof, said flexible member being formed at least in part of first fibers of ultra-high molecular-weight high tenacity material and at least second fibers which differ from said first fibers and are formed from a non-absorbable material, said first and second fibers being braided to form said elongated member.

2. The method of claim 1 wherein the molecular weight of said fibers is within the range of from about 500,000 to about 5 million.

3. The method of claim 2 wherein said fibers comprise high tenacity extended chain polyethylene fibers.

4. The method of claim 1 wherein said elongate member has an elongation to break below about 15%.

5. The method according to claim 1 wherein said elongate member is of a flat braided construction.

6. The method according to claim 1 wherein said elongate member is of hollow braid construction.

7. The method according to claim 6 wherein said hollow braid contains a core.

8. The method according to claim 1 wherein said elongated member is of spiroid braid construction.

9. The method according to claim 8 wherein said spiroid braid has a substantially circular cross-sectional shape.

10. The method according to claim 1 wherein said elongated member has a straight pull greater than about 35 kg.

11. The method according to claim 1 wherein said second non-absorbable fibers are formed from nylon.

12. The Method according to claim 1 wherein said second non-absorbable fibers are formed from polyester.

* * * * *

[About Us](#)[Products](#)[News](#)[Education](#)[My Arthrex](#)

User Name:

Password:

Search:

About Us

[Home](#) << [About Us](#)

Incorporated since 1984, Arthrex has been a privately held corporation committed to just one thing: providing the finest quality products and educational services to meet the special needs of orthopaedic surgeons and their patients. Arthrex has a focused dedication to creative product development and medical education with an experienced, devoted team of professionals who are truly committed to continuing this tradition.

New product innovation in arthroscopic surgery is the heart and soul of Arthrex, which has resulted in the development of over 2,000 products for arthroscopic and minimally invasive orthopaedic surgical procedures. Our goal is to make technically demanding surgical procedures easier, safer and reproducible.

Investing in Arthrex products means you have chosen a company committed to uncompromising quality and constant product innovation while providing you with the most competent technical customer support in the industry. Today our products are distributed throughout the U.S. and in over 60 countries worldwide.

Update

- ▶ [Mission](#)
- ▶ [Locations](#)
- ▶ [Careers](#)
- ▶ [Contact Us](#)
- ▶ [News](#)

[Privacy Policy](#) • [Legal & Ethics Notice](#) • [Contact Arthrex](#) • [Locations](#) • [Careers](#) • [Site Map](#) • [Related Links](#) • [Register](#) • [Help](#) • [Website](#)

EXHIBIT 16

EXHIBIT 17



HOME REGISTER LOGIN HELP PRIVACY POLICY



Product Information

Professional Resources

SEARCH

Advanced Search

Product Ordering

Contact Us

More Information
[DePuy Mitek, Inc., a Johnson & Johnson company](#)

Microsite

[Professional Education](#)

Related Websites

[ORTHOVISC®](#)

[Website Satisfaction Survey](#)

Company Home Page

[DePuy Mitek, Inc., a Johnson & Johnson company](#)

Company Information

[About DePuy Mitek](#)

[California Health Care Compliance Information](#)

[DePuy Mitek Employment Opportunities](#)

[Safe Harbor Policy](#)

Press Release

[DePuy Mitek Begins Pilot Study on New System For Articular Cartilage Restoration](#)

[Use of MILLAGRO™](#)

[Bioreplaceable Screw on the Rise](#)

Contact Us

[Contact Information](#)

[DePuy Mitek Locations](#)

Related Product Information

[Hand/Wrist Solutions](#)

[ORTHOVISC®](#)

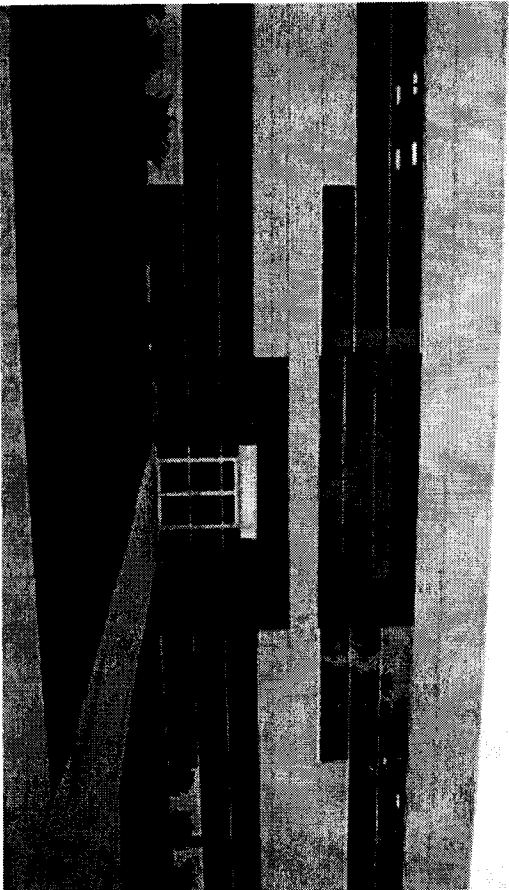
DePuy Mitek is a leading developer, manufacturer and marketer of innovative medical devices for surgery, with

focus on sports medicine and reconstruction. In 1985, Mitek Surgical Products, Inc. was the first company to develop and market implantable orthopedic devices built on new technology employing a nickel-titanium alloy known as Nitinol. Today the company's main products, suture anchoring implants, are recognized worldwide as the gold standard for tissue reattachment in a wide range of clinical indications. The DePuy Mitek Anchors are primarily used to reattach damaged ligaments and tendons in the shoulder, rotator cuff, wrist, thumb and ankle. Increasingly, DePuy Mitek's very small Micro Anchors are used for precise repair and reconstruction by hand, plastic and craniofacial surgeons.

DePuy Mitek also markets the innovative VAPR® System for precise, rapid soft tissue removal and modification with simultaneous control of bleeding. The wide selection of VAPR Electrodes facilitates access to regions of the shoulder, knee, wrist, elbow and ankle for use in a broad range of indications. The VAPR T family of electrodes can be used to thermally modify collagen in soft tissue.

In April 1995, Mitek was acquired by ETHICON, Inc., a Johnson & Johnson company. In 2003, DePuy Mitek became a part of the DePuy franchise, also within the Johnson & Johnson family. Our headquarters are in Raynham, Massachusetts, and we currently have manufacturing plants in Raynham, Massachusetts, Neuchâtel, Switzerland, and Nice, France.

• VAPR® Radiofrequency System



[Back to Homepage](#)

All contents copyright © Johnson & Johnson Gateway, LLC 2000-2006 unless otherwise noted. This site was written for U.S. healthcare professionals only. Click here for our [Privacy Policy](#) and [Legal Notice](#). If you have chosen this country and/or language view in error and need to return to the main menu click here. Capitalized product names are trademarks of Johnson & Johnson or its affiliated companies. Prescription products or in vitro diagnostics only unless otherwise noted in our [non-prescription product list](#).

EXHIBIT 18

About ETHICON

ETHICON, a global medical device company, has been a leader in surgical sutures (stitches) for more than 100 years. Today, we have expanded our expertise into wound management, women's health, and cardiovascular surgery. We have four business units that operate separately under the ETHICON umbrella, yet share the synergy of being not only part of ETHICON, but of Johnson & Johnson, the world's most comprehensive and broadly based manufacturer of healthcare products.

ETHICON enjoys a reputation for developing quality products to enhance the lives of patients and for providing outstanding service to customers. Headquartered in Somerville, New Jersey, ETHICON presently conducts business in 52 countries and employs approximately 11,000 employees in its various worldwide locations.

Select one of the following companies to learn more:

ETHICON Products
ETHICON Women's Health and Urology
Johnson & Johnson Wound Management
CARDIOVATIONS.

EXHIBIT 19

1 A. To the amount of surface area in the
2 multifilament braid and the potential for -- let's
3 just leave it at that: The amount of surface area
4 between a multifilament versus a monofilament.

5 Q. Does it have to do with the roughness of
6 the braid versus smoothness of the braid?

7 A. Less to do with that, more to do with the
8 fact that the multifilament braid has interstices
9 (sp) that, you know, could potentially harbor
10 bacteria, etcetera.

11 Q. Going back to this paragraph that begins
12 at Line 26, it then goes on to speak about, "For
13 example, multifilament sutures almost universally
14 possess a surface coat to improve handling
15 properties." Is improving handling properties one
16 of the specific properties of multifilament braids
17 that is -- that coating -- that this paragraph is
18 saying coating is designed to improve?

19 MR. BONELLA: Object to form.

20 A. I'm sorry.

21 Q. Let me rephrase that. That was --

22 A. Yeah. I'm sorry.

23 Q. It says, "For example, multifilament
24 sutures almost universally possess a surface
25 coating to improve handling properties." Do you

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4

COPY

5 DePUY MITEK, INC.,)
6 Plaintiffs,)
7 vs.)
8 ARTHREX, INC., a Delaware)
9 corporation,)
Defendants.)

10
11
12 DEPOSITION of DR. MARK G. STECKEL,

13 called as a witness by and on behalf of the
14 Defendant, pursuant to the applicable provisions of
15 the Federal Rules of Civil Procedure, before P.
16 Jodi Ohnemus, Notary Public, Certified Shorthand
17 Reporter, Certified Realtime Reporter, and
18 Registered Merit Reporter, within and for the
19 Commonwealth of Massachusetts, at the Courtyard
20 Marriott, 423 Speen Street, Natick, Massachusetts,
21 on Thursday, 26 January, 2006, commencing at 10:44
22 a.m.
23
24
25

1 Ethicon had multiple development programs going,
2 some of which were to make a product that were --
3 had better properties than silk, and silk has
4 really good handling properties. Some of them had
5 to do with higher strength sutures. Some of them
6 had to do with different biologic profiles in terms
7 of strength retention over time. And the initial
8 discussions were how can we address those types of
9 problems with a combination of fiber types.

10 So, the initial conversations -- and one
11 of the avenues that came out of that was this maybe
12 opportunity to have a suture that has strength
13 better than silk, but pliability like silk. So,
14 that was one of them.

15 Q. Okay.

16 A. And that was one that Al and Art had
17 considered in the past. Again, I'm not clear how
18 far they took that in the past, but they at least
19 considered that. And that was one that we elected
20 to pursue earlier than later, because we had the
21 materials, essentially. We thought it was good
22 opportunity.

23 Q. So, if I understand your testimony -- at
24 least at the very beginning stage you wanted
25 something that was stronger than silk but handled

1 as well as silk, is that --

2 A. That was certainly one of the embodiments
3 we were going after.

4 Q. As the -- as the project -- as the
5 project progressed and as you applied for a patent,
6 is it correct that you were trying to get something
7 that handled better than a homogenous braid but
8 didn't lose strength -- appreciably lose strength
9 from the conventional homogenous braid?

10 A. The overall project, yeah, I think that
11 was -- that would be a fair assessment of the
12 objective of the overall project.

13 Q. All right. And the conventional
14 homogenous braid that you were talking about that
15 you wanted to not lose appreciative strength then
16 was Ethibond, is that correct?

17 A. Right. Ethibond -- well, Ethibond, you
18 know, had good strength, but maybe not as good
19 handling properties as silk,.

20 Q. Right.

21 A. Silk had lower strength, good handle
22 properties, and again, one of the concepts was we
23 -- maybe we could get the best of both.

24 Q. All right. But as you applied for the 446
25 patent, was it the object there to have something

1 interest in how do you improve the knot strength of
2 them, and can you -- that was -- that was something
3 we discussed.

4 Q. I'm not sure I understand your answer.

5 A. Go ahead.

6 Q. And I'm trying to --

7 A. Sure.

8 Q. When you had this idea that you could
9 blend Dyneema together with PET, were you -- did
10 you believe it would make an acceptable suture or
11 an unacceptable suture?

12 A. No. We believed -- we believed that that
13 could offer a suture with straight tensile that was
14 better than Ethibond, and you know, could
15 potentially solve the knot issues, and again, that
16 was a generic view for all of the high-tenacity
17 fibers.

18 Q. You thought it was a good idea --

19 A. Yes. Yes.

20 Q. -- rather than a bad idea?

21 A. No, we viewed -- we viewed that as a
22 potential good idea.

23 Q. And you didn't think, Oh, that's a bad
24 idea.

25 MR. BONELLA: Objection. Asked and

Continued Deposition of:
Dr. Mark Steckel, Vol. II

February 3, 2006

Page 209

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4 DAY II

COPY

5 DePUY MITEK, INC.,)
6 Plaintiffs,)
7 vs.)
8 ARTHREX, INC., a Delaware)
9 corporation,)
Defendants.)

10
11
12 CONTINUED DEPOSITION of DR. MARK

13 G. STECKEL, called as a witness by and on behalf of
14 the Defendant, pursuant to the applicable
15 provisions of the Federal Rules of Civil Procedure,
16 before P. Jodi Ohnemus, Notary Public, Certified
17 Shorthand Reporter, Certified Realtime Reporter,
18 and Registered Merit Reporter, within and for the
19 Commonwealth of Massachusetts, at the Hilton Hotel,
20 25 Allied Drive, Dedham, Massachusetts, on Friday,
21 3 February, 2006, commencing at 9:06 a.m.

1 Q. Were the braids -- was a tipping put on
2 the braids?

3 A. There would not be tipping, since we never
4 intended to attach needles to this evaluation.

5 Q. Were the braids sterilized?

6 A. Typically at this level -- the answer is,
7 I believe, no. At this point in an evaluation, we
8 would typically evaluate presterile properties.

9 Q. Okay. Could you turn to Page 2638. So,
10 the fourth page of the --

11 A. Yes.

12 Q. -- fourth page of this -- the entry.

13 Under "Discussion," the first sentence says, "From
14 a braid processing viewpoint, the commingled yarn
15 was the least problematic braid, followed by the
16 yarn blend. The carrier blend presented the most
17 difficulties in core popping and braid looseness."

18 What did you mean by "The carrier blends
19 presented the most difficulties in core popping and
20 braid looseness"?

21 A. Core popping is a common braid defect.
22 You know, any braid text would -- would cover it.
23 The ability to adjust the tension on the yarn that
24 affects core popping was more difficult with the
25 carrier blend and the yarn blend than the

1 Q. Could you read her note for the record,
2 please.

3 A. Yes. "Being reviewed as potential new
4 product for Ethicon. May offer significant
5 advantages if technical problems of mixing of
6 materials with dissimilar stress/strain properties
7 can be overcome."

8 Q. Okay. Do you have an understanding of
9 what was meant by "-- if technical problems of
10 mixing of materials with dissimilar stress/strain
11 properties can be overcome"?

12 A. I believe she's referring to the tension
13 issues on processing the heterogeneous yarns.

14 Q. That we've discussed last week and earlier
15 today?

16 A. That would be my understanding.

17 Q. All right. And is it your understanding
18 that those --

19 A. Although this is Barbara's words, not
20 mine.

21 Q. That's what I'm trying to under -- to get
22 your understanding.

23 A. Yeah.

24 Q. And is it your understanding that those
25 technical problems with tension had not yet been

1 overcome as of February 8th, 1990?

2 MR. BONELLA: Object to the form.

3 A. I don't know if -- if Barbara at the
4 director level or manager level would have had
5 firsthand knowledge of that, so --

6 THE WITNESS: I'm sorry. Could you repeat
7 the question.

8 (Question read back.)

9 A. Once again, I think we're in the realm of
10 manufacturing requirements versus proof of concept
11 requirements in terms of have the technical
12 problems been overcome?

13 Q. Well, was it your understanding that --
14 well, do you understand -- do you know the basis of
15 Ms. Schwartz's comment, what that was based upon --
16 what her comment was based upon?

17 A. No, I'm inferring it from -- from the
18 comments and from what we've read.

19 Q. Okay. So, do you have an understanding
20 one way or another exactly what she was talking --
21 well, strike that.

22 MR. SABER: Why don't we take our break.

23 (Recess was taken.)

24 Q. Doctor Steckel, there came a time, of
25 course, when Ethicon applied for the 446 patent, of

1 **see that?**

2 A. Yes.

3 **Q. What's your understanding of what handling**
4 **properties are being referred to in that sentence?**

5 A. My understanding, because the surface
6 coating would be for knot handling, knot tie-down
7 handling properties.

8 **Q. Knot tie-down?**

9 A. Knot tie-down.

10 **Q. Anything else?**

11 A. Not to my understanding.

12 **Q. How about how well the knot slides, is**
13 **that one of the things that --**

14 A. Oh, yeah. That's part of knot tie-down.

15 **Q. Why don't you explain to me what is part**
16 **of knot tie-down.**

17 A. Okay. Yeah. I mean, knot tie-down refers
18 to the properties of a suture during the tying
19 process, which would include the force, smoothness,
20 roughness when one arm of the suture is being
21 pulled against the second arm of the suture.

22 **Q. How about is -- is coating designed to**
23 **help the -- the suture go through tissue more**
24 **easily?**

25 MR. BONELLA: Objection. Calls for expert

EXHIBIT 20

ETHICON, INC.

a Johnson & Johnson company

SOMERVILLE - NEW JERSEY - 08876-0151

RECEIVED

FEB 8 1990

BARBARA SCHWARTZ

February 8, 1990

IDEA APPRAISAL

TO: Dr. B. Schwartz

SUBJECT: Idea Number 2749

Please assess the merits of the attached idea and recommend a course of action with comments on the reasons for your recommendation.

The merit evaluation should be from a Technical, Marketing, Surgical or other standpoint - depending upon your own expertise.

Please return the idea description together with the completed Appraisal Form within three days.

Charles G. Fritz, Ph.D.
Secretary
Idea Review Board

RECOMMENDATION

COMMENTS

☒ Pursue actively

☐ Defer until _____

☐ Deactivate

Being reviewed as potential
new product for Ethicon. May offer
significant advantages if technical
problems of ~~the~~ mixing 2 materials
with dissimilar stress/strain
properties can be overcome.

B. Schwartz
2/7/90

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS

DMI095020

CONFIDENTIAL

EXHIBIT 21

BOOK NO. 2175

ETHICON, INC.
a Johnson & Johnson company

Issued to Mark Steckel

Covering the Period

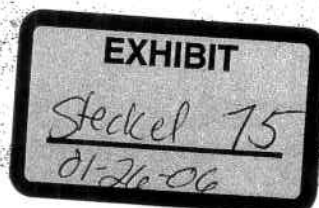
Feb 29, 1988 to _____

EXACT COPY

CONFIDENTIAL

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

This notebook is the property of ETHICON INC. and constitutes part of its permanent records.
It should be returned to the company when not in active use, or upon request.



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI002605

Page

Book No.

0175

Project No. CBE Experiment No. _____ Date 2/2/89
 Subject PET/PTFE COMPOSITE BRAIDS
 Purpose EXPLORATORY EVALUATION OF VARIOUS PROCESS METHODOLOGIES

BACKGROUND - PAGE 8

ADDITIONAL PET/PTFE COMPOSITES BRAIDS WERE PRODUCED UTILIZING 1) CARRIER BLEND, 2) YARN BLEND, 3) COMMINGLING TECHNOLOGIES. COMPOS OF 100% PET AND 100% PTFE WERE ALSO PRODUCED. FIBER SUPPLY/TYPE/DENIER, BRAID CONSTRUCTION, SLOVA CONDITION, H.S. CONDITIONS WERE CONSTANT FOR ALL BRAIDS.

THE FOLLOWING IS THE YARN INFORMATION/DESCRIPTION:

COMPOSITE BRAID EVALUATION
YARN A DESCRIPTION

MGS ID#	FIBER A	FIB A DENIER	FIB A FILAM COUNT	FIB A SOURCE	FIB A LOT #	FIB A COLOR	FIB A TWIST LEVEL (TPI)	FIB A TWIST DIRCT (S/Z)	FIB A ENTANG LEVEL
CBE-15	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *	0	
CBE-16	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *	0	
CBE-16A	PET	70	34	DUPONT		WHIT	0.0 *	R14	
CBE-17	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *	0	
CBE-18	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *	0	
CBE-19	PET	70	48	SUT DEV	SPZ-305	GREN	0.0 *	0	

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

COMPOSITE BRAID EVALUATION
YARN B DESCRIPTION

MGS ID#	FIBER B	FIB B DENIER	FIB B FILAM COUNT	FIB B SOURCE	FIB B LOT #	FIB B COLOR	FIB B TWIST LEVEL (TPI)	FIB B TWIST DIRCT (S/Z)	FIB B ENTANG LEVEL
CBE-15	PTFE	110	15	DUPONT	1T138	WHIT	0.0 *	0	
CBE-16	PTFE	110	15	DUPONT	1T138	WHIT	0.0 *	0	
CBE-16A	PTFE	115	15	DUPONT	1T138	WHIT	0.0 *	0	
CBE-17	PTFE	115	15	DUPONT	1T138	WHIT	0.0 *	0	
CBE-18	PTFE	115	15	DUPONT	1T138	WHIT	0.0 *	0	
CBE-19	PTFE	115	15	DUPONT	1T138	WHIT	0.0 *	0	

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI002635

Investigator

Witness

[Signature]
 Donald Britt

Date

Date

2/2/89

3-15-90

Book No.

2175

Project No. CBE

Experiment No.

Date 2/2/89

Subject PET/PTFE COMPOSITES

Purpose

CONTINUED

THE ABOVE BRAIDS WERE SLOUNED IN SKIN FORM
IN A BEAKER W/ AN AQUEOUS DETERGENT SYSTEM.
FOLLOWING SLOUNING & ONLY, THE BRAIDS WERE
HOT-STRETCHED AS FOLLOWS:

COMPOSITE BRAID EVALUATION
HOT STRETCH CONDITIONS

MGS ID#	HOT-STRETCH %	ROLL		ROLL		ROLL		ZONE		ZONE		ZONE	
		1	2	1	2	1	2	1	2	1	2	3	4
		FPM	FPM	# OF WRAPS	# OF WRAPS			TEMP (C)	TEMP (C)	TEMP (C)	TEMP (C)		
CBE-15	30	9.0	11.7	8	12	125	150	190	225				
CBE-16	30	9.0	11.7	8	12	125	150	190	225				
CBE-16A	30	9.0	11.7	8	12	125	150	190	225				
CBE-17	30	9.0	11.7	8	12	125	150	190	225				
CBE-18	30	9.0	11.7	8	12	125	150	190	225				
CBE-19	30	9.0	11.7	8	12	125	150	190	225				

THE HOT-STRETCHED BRAIDS WERE CHARACTERIZED
PER STANDARD SUTURE TEST METHODS:

COMPOSITE BRAID EVALUATION

PHYSICAL PROPERTY CHARACTERIZATION

MGS ID#	USP ULTIMAT		INTRIN ULTIMAT		INTRIN		KNOT ULTIMAT		KNOT		BSR		BSR		PICKS TOTAL	
	DIAM	TENSILE	TENSILE	KNOT	KNOT	CONVER	ELONGAT	STRAND	STABIL		CONTL	21 DAY	21 DAY	21 DAY	PER	DENIER
	(MILS)	STREN	STREN	STREN	STREN			BENDING							INCH	
		(LBS)	(PSI)	(LBS)	(PSI)	(%)	(%)	(GMxCM2)	(# THROWS)		(LBS)	(LBS)	(%)			
CBE-15	18.6	14.14	51758	9.64	35254	68	34	2.24E-2	5		0.00	0.00			44	2529
CBE-16	19.1	13.07	45460	9.52	33116	73	30	2.20E-2	5		0.00	0.00			45	2694
CBE-16A	0.0	0.00	0	0.00	0	0	0	0.00			0.00	0.00			41	2565
CBE-17	19.9	13.88	44850	11.02	35600	79	39	1.28E-2	5		0.00	0.00				
CBE-18	19.5	21.30	71295	13.54	45241	63	27	3.00E-2	4		0.00	0.00				
CBE-19	20.6	7.37	21460	5.96	17763	79	57	1.12E-2	7		0.00	0.00			39	2970

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

Investigator

Witness

[Signature]
Crawford Britt

Date

Date

2/2/89

3-15-90

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No. 04-12457 PBS

DMI002637

Project No. CBE Experiment No. _____
Subject PET/PTFE COMPOSITES
Purpose CONTINUED:

Date 2/2/89Page _____
Book No. _____

2175

DISCUSSION:

FROM A BRAID PROCESSING VIEWPOINT, THE COMMINGED YARN WAS THE LEAST PROBLEMATIC BRAID FOLLOWED BY THE YARN BLEND. THE CARRIER BLEND PRESENTED THE MOST DIFFICULTIES IN CORE COPPING AND BRAID LOOSENESS. THE COMMINGED YARN DID POSSESS REGIONS WHERE THE YARNS SEPARATED RESULTING IN BRAIDING DIFFICULTY AND ROUGHNESS.

FROM A PROPERTY VIEWPOINT, THE INTRINSIC TENSILES OF THE THREE COMPOSITES WERE CLOSE AND APPROXIMATED A RULE OF MIXTURES AVERAGE OF THE TWO CONTROL BRAIDS. THE CARRIER BLEND WAS APPROX 10% HIGHER. INTRINSIC -KNOT STRENGTHS WERE VERY SIMILAR AMONG THE COMPOSITES AND WERE 75-80% OF THE PET CONTROL KNOT STRENGTH. THE COMM. HAD THE HIGHEST KNOT CONVERSION (72%). THE BENDING RIGIDITY OF THE COMMINGED WAS HALF THE OTHER TWO COMPOSITES, PERHAPS REFLECTING THE MORE HOMOGENEOUS MIXTURE OF THE TWO COMPONENTS. ALL 3 COMPOSITES HAD KNOT SECURITIES OF 5 THOUS - SIGNIFICANTLY BETTER THAN 2 FOR 100% PTFE.

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No.04-12457 PBS

DMI002638

Investigator

Witness

[Signature]
Crawford Britt

Date

Date

2/2/893-15-90

Project No. CBE Experiment No. _____ Date 12/13/89
 Subject CONTIN FROM 2175-56
 Purpose _____

PROPERTIES:

THE DIE-DRAWN COMPOSITE BRAID HAD SUPERIOR HANDLING PROPERTIES RELATIVE TO SILK AND ETHIBOND, WHICH IS DEMONSTRATED QUANTITATIVELY IN FIG 2 OF THE KAWASATA BENDING RIGIDITY RESULTS. THE INTRINSIC TENSILE AND KNOT STRENGTHS WERE 87 KSI AND 48 KSI RESPECTIVELY. THE COMPOSITE ALSO RANKED BETTER THAN THE SILK AND ETHIBOND IN KNOT TIE-DOWN, EVEN WITHOUT A COATING.

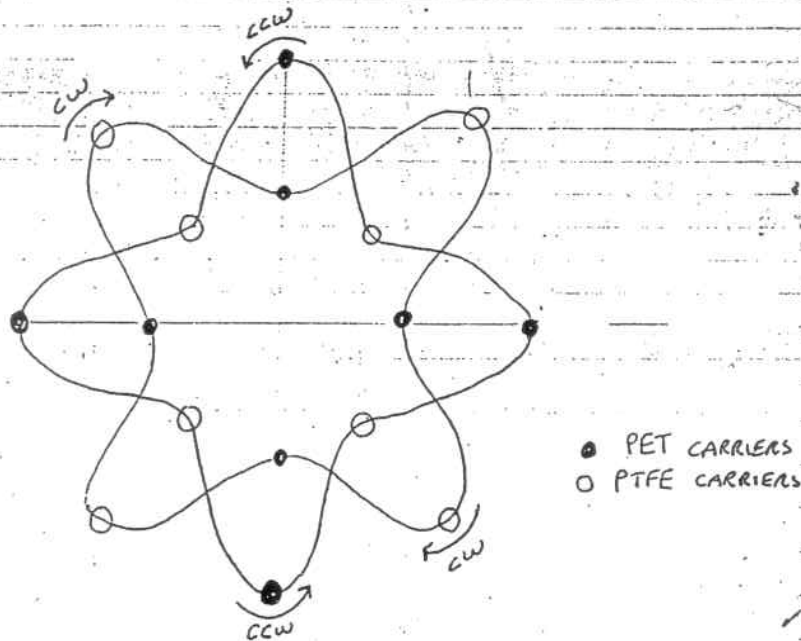


FIG. 1. SCHEMATIC OF CARRIER LAY OUT FOR BALANCED COMPOSITE BRAID.

CONFIDENTIAL -
 NON-PATENT
 PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No. 04-12457 PBS

DMI002666

Investigator

Witness

[Signature]
 Crawford Britt

Date

Date

12/13/89

3-15-90

EXHIBIT 22



~~838511~~
838511

- 1 -

TITLE OF THE INVENTION

STERILIZED HETEROGENEOUS BRAIDS

5 BACKGROUND OF THE INVENTION

10 This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

15 Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring
20 filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case
25 where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

30 Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

ETH-782

2

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000016

- 2 -

FFB
B
FB

U.S. Patent 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Patent 4,624,256
5 discloses a suture coating copolymer of at least 90 percent ϵ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically
10 used to prepare bioabsorbable coatings for multifilament sutures.

FB 15

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Patent 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of
20 multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

FB

25 More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Patent 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of
30 low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite

ETH-782

3

- 3 -

5 sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by Figure 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

10 Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

20 All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

ETH-782

- 4 -

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying

ETH-782

- 5 -

the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved
5 pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are
10 useful as surgical sutures or ligatures, as well as for the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

DECL 15

BRIEF DESCRIPTION OF THE DRAWINGS

F

Figure 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

20

Figure 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

25

Figure 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

30

DECL

DETAILED DESCRIPTION OF THE INVENTION

F

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at

ETH-782

6

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000020

- 6 -

least two sets of dissimilar yarns mechanically blended by
intertwining the dissimilar yarns in a braided
construction. The yarns are continuous and discrete, so
therefore each yarn extends substantially along the entire
5 length of the braid and maintains its individual integrity
during braid preparation, processing and use.

FB
C
10 The heterogeneous braids of this invention can be
conventionally braided in a tubular sheath around a core
of longitudinally extending yarns, although such a core
may be excluded, if desired. Braided sheath sutures with
central cores are shown in U.S. Patent Nos. 3,187,752;
4,043,344; and 4,047,533, for example. A core may be
advantageous because it can provide resistance to
15 flattening, as well as increased strength. Alternatively,
the braids of this invention can be woven in a spiral or
spiroid braid, or a lattice braid, as described in U.S.
Patent Nos. 4,959,069 and 5,059,213.

FB
20 The dissimilar yarns of the first and second set of yarns
are braided in such a manner that at least one yarn from
the first set is directly intertwined with, or entangled
about, a yarn from the second set. Direct mechanical
blending of individual, dissimilar yarns therefore occurs
25 from the interweaving and interlocking of these dissimilar
yarns, enhancing yarn compatibility and the overall
physical and biological properties of the heterogeneous
braid. Preferably, every yarn from the first set is in
direct intertwining contact with a yarn of the second set
30 to achieve the maximum degree of mechanical blending of
the dissimilar yarns.

The first and second fiber-forming materials which make up
the filaments of the first and second set of yarns,

ETH-782

7

- 7 -

respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

5 The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance
10 dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable
15 hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ -caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids
20 exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

25 Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve
30 the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle

ETH-782

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000022

- 8 -

of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polychlorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below

ETH-782

- 9 -

about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

10

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of Figure 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

25

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of Figure 1 are dispensed upward

30

ETH-782

10

- 10 -

with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

4C 5 In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid.

4C 10 In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

15 Advantageously, as illustrated in Figure 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 4C 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

20 Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using 25 from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns 30 composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

ETH-782

- 11 -

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing

ETH-782

12

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000026

- 12 -

stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Patent 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is

ETH-782

- 13 -

determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

5

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

15

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Patent 4,470,941.

CONTROL I

CL

PB33

30

FIBER MATERIALS: An 8x0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

P

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each

ETH-782

14

- 14 -

B
B
B
5
carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225 C°.

CL
PB 33
10
P
B 15
CONTROL II

FIBER MATERIALS: An 8x0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

CL
20
PB 33
B 25
P
30
B
B
EXAMPLE I

FIBER MATERIALS: An 8x0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm.

ETH-782
15

- 15 -

The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300 C° and for a longer residence time to facilitate melting of the PET fibers.

ETH-782

- 16 -

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gmXcm ²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.87			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (Vf_a) (P_a) + (Vf_b) (P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in Figure 2, which shows a plot of tensile strength versus

ETH-782

- 17 -

volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

5 Surprisingly, the bending rigidity of the heterogeneous
braids in EXAMPLES I and II do not follow the rule of
mixtures, and show an enhanced bending rigidity relative
to the weighted average of its components. This is shown
10 in Figure 3 as a plot of bending rigidity versus %PTFE in
the braids. Bending rigidity is the inverse of
pliability, and is obtained by measuring the slope of the
bending moment-radius of curvature plot of a suture strand
in pure bending. Hence lower bending rigidity relates to
15 a more pliable suture, which is a highly desirable
property. The mechanism of this enhanced pliability is
believed to be internal lubrication of the braid by the
"solid lubricant" behavior of the low surface energy PTFE.

FB
20 U.S. Patent 4,470,941 discloses the preparation of a
"composite" suture with a monofilament-like surface made
from multifilament yarns. The composite suture is
composed of two different synthetic polymer fibers, which
is thermally processed to melt one of the fibers to form
a continuous matrix. This process was utilized to produce
25 the PRIOR ART I example, the data of which is shown in
Table 1 and Figure 3. It is observed that the melting of
the PET fibers significantly increases the braid bending
rigidity due to the bonding of the "non-melted" fibers
together, hence resulting in a less pliable braid of
30 diminished utility.

ETH-782
18

- 18 -

WHAT IS CLAIMED IS:

1. A heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and:
- a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and
- b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.
2. The heterogeneous braid of claim 1 wherein the first and second fiber-forming materials are nonmetallic.
3. The heterogeneous braid of claim 2 wherein the first and second fiber-forming materials are synthetic fiber-forming polymers.
4. The heterogeneous braid of claim 3 wherein the synthetic fiber-forming polymers are bioabsorbable.
5. The heterogeneous braid of claim 4 wherein the bioabsorbable polymers are derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactide, p-dioxanone, ϵ -caprolactone, trimethylene carbonate, and mixtures thereof.
6. The heterogeneous braid of claim 3 wherein the fiber-forming polymers are nonabsorbable.

ETH-782

19

- 19 -

3
7. The ~~heterogeneous braid~~ ^{surgical suture} of claim ~~6~~ ¹ wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4
8. The ~~heterogeneous braid~~ ^{surgical suture} of claim ~~7~~ ³ wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

9. The heterogeneous braid of claim 8 wherein the first set of yarns is PTFE, FEP, PEEK, PVDF, PETFE, PP or PE.

5
10. The ~~heterogeneous braid~~ ^{surgical suture} of claim ~~9~~ ⁴ wherein the first set of yarns is PTFE.

6
11. The ~~heterogeneous braid~~ ^{surgical suture} of claim ~~10~~ ⁵ wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7
12. The ~~heterogeneous braid~~ ^{surgical suture} of claim ~~11~~ ⁶ wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

13. The heterogeneous braid of claim 12 wherein the second set of yarns is PET, nylon or aramid.

8
14. The ~~heterogeneous braid~~ ^{surgical suture} of claim ~~13~~ ¹⁴ wherein the second set of yarns is PET.

15. The heterogeneous braid of claim 14 wherein each yarn from the first set is in direct intertwining contact with a yarn from the second set.

16. The heterogeneous braid of claim 15 wherein the braid encloses a core of longitudinally extending yarns.

ETH-782

22

- 20 -

17. The heterogeneous braid of claim 16 wherein the longitudinally extending yarns are PET.

9 surgical suture 8
18. The heterogeneous braid of claim 17 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10 surgical suture 9
19. The heterogeneous braid of claim 18 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11 surgical suture 1
20. The heterogeneous braid of claim 19 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

21. A surgical suture comprising the heterogeneous braid of claim 1.

22. A surgical suture comprising the heterogeneous braid of claim 19.

23. The surgical suture of claim 21 wherein the suture is attached to a needle.

8
24. The surgical suture of claim 22 wherein the suture is attached to a needle.

ETH-782

23



07/838,511

- 21 -

ABSTRACT

SA

5 Heterogeneous braided multifilament of first and second
set of yarns mechanically blended by braiding, in which
first and second set of yarns are composed of different
fiber-forming materials.

PA

10 Heterogeneous braids are useful for preparation of
surgical sutures and ligatures.

EA

15

20

25

30

ETH-782

EXHIBIT 23



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/838,511	02/19/92	HUNTER	A ETH-782

EXAMINER	
RAIMUND C. [Signature]	
ART UNIT	PAPER NUMBER
1504	

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

DATE MAILED: 07/08/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 24 are pending in the application.
Of the above, claims 1 - 20 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 21 - 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1 - 24 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Serial No. 838,511

-2-

Art Unit 1504

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-20, drawn to a heterogeneous braid, classified in Class 57, subclass 243.

II. Claims 21-24, drawn to a surgical suture, classified in Class 600, subclass 231.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

Serial No. 838,511

-3-

Art Unit 1504

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Matthew S. Goodwin on June 23, 1992 a provisional election was made without traverse to prosecute the invention of Group II, claims 21-24. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Serial No. 838,511

-4-

Art Unit 1504

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Burgess (U.K. Patent Application No. 2,218,312A).

Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon. Such a braid is disclosed to have the low stretchability of polyethylene and the low coefficient of friction of polyester. (See page 1). It is therefore known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber.

Braided sutures are well known in the art. Many of the requirements of sutures are comparable to those of fishing line—strength, low stretchability, flexibility, low coefficient of friction etc. Indeed, many of the same materials are used for both of these applications. It would therefore have been

Serial No. 838,511

-5-


Art Unit 1504

obvious, in view of Burgess, to use a heterogeneous braid for a suture. Claims 21 and 23 are therefore unpatentable over Burgess.

Synthetic, fiber forming polymers are widely employed as filaments in braided sutures. In German Patent Application DE 2949920A1, for example, surgical sutures made from braided polytetrafluoroethylene (PTFE) fibers or polyester fibers are disclosed. As polyester fibers are noted for their strength and PTFE fibers for their low coefficient of friction, it would have been obvious to use a braid comprising both types of filaments as a suture.

It is also known in the art to a braid around longitudinally extending core filaments. Ohi et al, for example, disclose a core comprising a plurality of synthetic fiber filaments (column 1, lines 57-60). Polyester filament are specifically disclosed (column 2, lines 4-9). It would therefore have been obvious to dispose a heterogeneous braid comprising polyester and polytetrafluoroethylene fibers around a core of polyester fibers to form a suture. Claims 22 and 24 are therefore unpatentable over Burgess.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.


Chris Raimund:jp
July 06, 1992



DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No.04-12457 PBS

DMI000190

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

EXHIBIT 24



ETH-78

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: 838,511 ✓

Art Unit: 1504

Filed : February 19, 1992 ✓

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 6, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

(Signature)

August 6, 1992
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

RECEIVED
AUG 17 1992
GROUP 150

AMENDMENT

Dear Sir:

Responsive to the Office Action of July 8, 1992, please reconsider the above-identified application in view of the following remarks.

REMARKS

1. Restriction to the invention of either Group I, claims 1-20, or Group II, claims 21-24, was required. Applicants reaffirm without traverse to prosecute the invention of Group II, claims 21-24. This election is made without prejudice to Applicants' right to file a divisional application directed to the non-elected invention of Group I, claims 1-20.

2. Claims 21-24 were rejected under 35 USC §103 as being unpatentable over Burgess. The Examiner has asserted that it would have been obvious in view of Burgess to use a heterogeneous braid for a suture. Applicants respectfully traverse this rejection.

DePuy Mitek, Inc. v. Arthrex, Inc.

C.A. No.04-12457 PBS

DMI000194

The Examiner mistakenly believes that the requirements for a braided suture are comparable to those of a fishing line. However, nothing could be further from the truth.

One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement may be the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact. If the knot fails, then the wound can reopen and consequently the braided suture has failed as well.

Applicants recognized the importance of knot strength when attempting to overcome the shortcomings of the braided sutures disclosed in the art. In preferred embodiments of the invention, Applicants' claimed suture exhibits improved handling properties without sacrificing physical strength or knot security (see the specification at page 5, lines 4-7). In addition, numerous braided sutures were tested to determine their knot strength and knot security (see the examples at the end of the specification). The determination of knot security is described in the specification at page 12, lines 26-33.

In contrast, knot strength is not even mentioned in Burgess. Although it may be argued that it may be necessary to secure a knot on a fishing line to hold the hook to the line, the security and strength of the knot are not nearly as critical for this application. In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below.

Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability (see Burgess at page 1, lines 12-13). Although this thread has great strength properties, it suffers from

elongation, or low stretchability, are important criteria. Low elongation is an important requirement for a fishing line because it makes it possible for the fisherman to apply force on the hook when, for example, the fish is caught. If the line were stretchable, then the force exerted by the fisherman would be taken up by the stretching action of the line. This would clearly be an undesirable property for a fishing line to exhibit. Therefore, the property requirements for fishing line yield a braid with poor knot strength and security, and the requirements for sutures yield a braid which has by necessity excellent knot strength and security.

In addition to the contrasting requirements for braided sutures and fishing line resulting from the critical need to tie strong and secure knots on braided sutures, other requirements concerning the knot make the braid for a fishing line unsuitable for use as sutures. For example, a surgeon must be able to make a conventional square knot at a very fast pace for patient safety. Clearly, a knot on a fishing line for a hook can be made at a much slower pace, and with a much more complex knot. Also, it is necessary during suturing to form a pre-knot on the braided suture, and the pre-knot must be subsequently slid down the suture until it is adjacent the body tissue desired to be stitched. Once the knot is placed at the desired location, additional throws on the knot can be added for knot security. This requires a braided suture which is stretchable and resilient so that this operation can be performed. Obviously, there is no such similar requirement for a fishing line.

In view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a

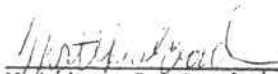
in error and therefore it should be withdrawn.

It is noted that the Examiner has discussed German Patent Application DE 2949920 A 1 and Ohi et al. as evidence of the state of the art concerning the types of filaments used in braided sutures, and core/sheath braid construction. Applicants do not wish to rely on these specific limitations set forth in claims 22 and 24 for patentability, but instead rely on the inventive features set forth in the broader independent claim, claim 21.

Accordingly, for the reasons set forth above, Applicants respectfully request the Examiner to withdraw the rejection of claims 21-24 under 35 USC 103 as being unpatentable over Burgess.

3. Since all formal requirements appear to have been met, except for the submission of formal drawings, and claims 21-24 are patentable over the art of record, Applicants respectfully solicit a Notice of Allowability.

Respectfully submitted,


Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

EXHIBIT 25



ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511

Art Unit: 1504

Filed : February 19, 1992

Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal B. Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

This amendment is responsive to the Office Action of March 18, 1993.

IN THE CLAIMS

Please amend claim 2) as follows:

(Once Amended)

1. A surgical suture [comprising] consisting essentially of a [the] heterogeneous braid [of claim 1] composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

REMARKS

4. Please note that the attorney prosecuting this application for the assignee, Johnson & Johnson, is now Hal Brent Woodrow (Reg. No. 32,501). This change has been authorized by the Associated Power Attorney submitted herewith. No change in the address for correspondence is necessary.

Claim 21 has been amend to place this claim in proper form for allowance. Claim 21 as amended claims a heterogeneous braid composed of a first and second set of yarns. The first set of yarns are made of a fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP, and PE materials. The second set of yarns are made of a fiber-forming material selected from the group consisting PET, nylon and aramid materials. Support for there amendments may be found in the specification on page 4, lines 12-22 and page 8, lines 3-23. Accordingly, applicants request entry of this amendment and reconsideration of claim 21.

The rejection of claim 21 under 35 U.S.C. §102(e) as being anticipated by Kaplan et al. has been reviewed. However, applicants respectfully submit that claim 21 as amended is not anticipated by Kaplan. Kaplan, as stated by the Examiner, describes a connective tissue prosthesis comprising a braided sheath yarn component and a core yarn component. The sheath yarn being a biocompatible yarn that is bioabsorbable or semi-bioabsorbable (column 9 lines 10-12). In one embodiment the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition (column 9 line 25-27). Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn. Accordingly, Kaplan et al. does not anticipate claim 21 under 35 U.S.C. § 102(e). Therefore, applicants request reconsideration and withdrawal of the rejection of claim 21 as being anticipated by Kaplan et al.

Applicants have also reviewed the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al. However, applicants respectfully submit that claims 21-24 are patentable over these documents.

Doddie et al. describes (column 9, lines 46-56) multifilament sutures composed of p-dioxanone and/or 1,4 dioxepan-2-one and alkyl substituted derivatives that may be woven, braided or knitted, either alone or in combination with nonabsorbable fibers. Although Doddie is a significant contribution to the art, Doddie does not describe heterogeneous braids formed from a first set of yarn composed of a plurality of filaments formed from materials selected

from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and a second set of yarn composed from a plurality of filaments formed from materials selected from the group consisting of PET, nylon and aramid. Accordingly, Doddi alone would not render the present invention obvious.

Kaplan et al. as discussed previously describes a prosthesis comprising a core component and a braided sheath component. The sheath component which is designed to "erode over time" (column 9, line 52) to leave only the nonabsorbable core component. The sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments. Applicants, therefore, respectfully submit that Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e. PTFE) and a second set of nonabsorbable yarn (i.e. PET). In fact, Kaplan teaches away from this combination.

In column 2, Kaplan describe one of the objects of their invention as being "a prosthesis being formed of a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-absorbable sheath yarn so as to exhibit the stress-strain properties of natural tissue" (column 2, lines 36-41). In column 4, Kaplan describes fluorinated hydrocarbons, polypropylene and polyethylene as elastic core polymers as opposed to the inelastic sheath polymers desired in the sheath. Thus, Kaplan appears to suggest that the sheath yarns listed by the applicant in claim 21 should not be used as in sheaths. Applicants respectfully submit that in view of Kaplan teaching away from the present invention that the combination of Kaplan with Doddi does not render the present invention obvious. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 21-24.

The citation of Block (U.S. Patent No. 3,527,650) has also been considered, but is respectfully submitted to be non-analogous art. Block describes the use of PTFE particles on the external surface of a PET suture as a lubricant. Block, however, does not suggest or disclose PTFE fiber as having a lubricating effect. Therefore, Block's use of PTFE particles does not suggest or disclose the use of PTFE fibers in braids.

Applicants also wish to alert the Examiner to the applicants' intent to change the inventorship because of the reduced scope of the claims. Dennis D. Jamiolkowski will no longer appear as an inventor if the present claims are allowed. Papers to effectuate this changed inventorship will be submitted when one or more of the present claims are indicated to be allowable.

Respectfully requested,

Hal B. Woodrow
Hal B. Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
Date: August 31 1995

EXHIBIT 26

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.

COPY

DEPOSITION OF: DONALD GRAFTON
DATE: March 14, 2006
TIME: 8:38 a.m. to 1:23 p.m.
LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112
TAKEN BY: Plaintiff
REPORTER: Deborah A. Krotz, RPR, CRR
VIDEOGRAPHER: Gene Howell, CLVS

1 and tensile strength; right?

2 A. Yes.

3 Q. Didn't that come up in your testing?

4 A. I don't recall.

5 Q. What was your involvement in the development of
6 FiberWire?

7 A. It was my idea.

8 Q. When you say it was your idea, what do you mean
9 by that?

10 A. I'll give you -- Would you like the story on how
11 FiberWire came about?

12 Q. Sure.

13 A. We were having issues from customers with the
14 Tevdek suture being low tensile strength as compared to
15 competitors' suture anchors with suture, primarily
16 Ethicon.

17 Q. Ethibond?

18 A. Ethibond. This was numerous complaints from
19 friendly surgeons, not -- not a massive amount of
20 complaints, but it was determined that the tensile
21 strength of the suture was not as good as the Ethicon
22 Ethibond suture.

23 Q. When you say friendly, do you mean friendly to
24 Arthrex?

25 A. Yes. And I had gotten a phone call from a Dr.

1 Deberdino who was a surgeon at Fort Sam Houston, San
2 Antonio. His -- his comments were that he had tied three
3 knots the previous afternoon using the FASTak product of
4 Arthrex -- that's a glenoid labrum device -- and had broke
5 the knots on all three of them. And -- you know -- he
6 said it kind of jokingly. He said, "And I didn't even
7 work out the day before."

8 And so he was trying to be nice about it, but
9 bottom line was your suture sucks. Okay?

10 And so -- you know -- we're in a position where
11 we need to find a suture that will be competitive. I had
12 been to Pearsalls many times working on bioabsorbable
13 products. This was the time that you referred to earlier
14 where I said three to five, and was familiar with suture
15 manufacturing, the steps required to manufacture a suture.

16 One of the trips there, Mr. Lyon had pointed out
17 to me a -- the other products they manufactured, which was
18 fishing line and silk used in decorated drapes. The
19 fishing line used a ultra-high molecular weight
20 polyethylene material that was very strong, and I -- at
21 some point, it was decided that we would try some of that
22 for a suture.

23 I had Pearsalls, mainly through Brian, as being
24 the manufacturing person --

25 Q. Brian Hallett?

1 A. That's correct -- make some Size 2 braided
2 material, send to me, and at the -- coincidentally, at the
3 same time, I had a Dr. Steve Burkhart from San Antonio and
4 a Dr. Casey Chan, who is a R & D guy in knot testing and
5 suture. They were -- they were at Arthrex at the time
6 when this material showed up.

7 We tested the material. The strength was
8 excellent. The knot slippage was very poor, would not
9 hold a knot.

10 So at that point in time, it looked like we would
11 not be able to use an alternative material of ultra-high
12 molecular weight polyethylene because the slippage of the
13 material -- because of the slippage of the material tested
14 with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at
15 that point in time, the -- the product was -- was on hold.

16 I was on a trip to Chicago to the national sales
17 meeting, and I had this idea of adding PET to the
18 ultra-high molecular weight polyethylene to enhance the or
19 reduce the knot slippage of the product. I sent an e-mail
20 to Dr. Steve Burkhart and suggesting that since he was
21 familiar with the testing we had done very recently with
22 just the ultra-high molecular weight PE, of adding the
23 PET, and his -- I'll never forget the e-mail. He thought
24 that was a killer idea.

25 And so I had asked then at that time for Brian

1 A. Yes.

2 Q. It's not like they had a product that they could
3 just give to you?

4 A. No.

5 Q. In your letter, you say you tested the samples of
6 Dyneema. Do you see that?

7 A. Yes.

8 Q. And then you say, "Can you build a 25 percent
9 Dyneema/75 percent polyester blend in Size 2 that is very
10 flexible (like the existing suture or the Ethicon sample)
11 and send it to me to test"; do you see that?

12 A. Yes.

13 Q. Does that Ethicon sample, does that refer to an
14 Ethibond?

15 A. Yes.

16 Q. And you say, "If we get the" -- "If we can get
17 this blend correct, we will have a terrific advancement in
18 suture for our soft tissue anchors"; do you see that?

19 A. Yes.

20 Q. What did you mean by that?

21 MR. SOFFEN: Objection; vague. It states what it
22 states. What's the question?

23 Q. Do you understand the question?

24 A. I'm not sure what -- what you're asking.

25 Q. I would like to know what you mean by in your

1 letter when you said, "If we can get this blend correct."
2 You asked them for a 25 percent Dyneema/75 percent
3 polyester blend in Size 2 that's very flexible. And then
4 you said, "If we can get this blend correct, we will have
5 a terrific advancement."

6 What did you mean by "If we can get this blend
7 correct"?

8 A. The optimization of the two materials. If you
9 had the knot strength, loop security, and tensile
10 strength, as well as the tactile feel of the suture all
11 superior to what was on the market, then it would be a
12 superior product.

13 Q. Wait a second. You said optimization of two
14 materials.

15 A. (Witness nods head affirmatively).

16 Q. At this point in time, November 1998, were you
17 trying to vary the amount and type of the Dyneema and
18 polyester in the braid in order to get the best
19 properties?

20 A. During -- during the -- during that period of
21 time, yes.

22 Q. So you were balancing off the properties of each
23 material to try to get the optimum properties --

24 A. Tensile strength.

25 Q. To get the optimum tensile strength?

EXHIBIT 27

Based upon QAD information as of 6/10/05
1st Invoice date per item

ITEM	DATE INVOICED	INVOICE	ORDER #	LOT/SERIAL	SITE	CUSTOMER
AR-11796	3/11/2004	IV731910	S709391	1229040700	N001	02000073
AR-11797	3/23/2005	IV952262	S931236	1229050600	N001	02000014
AR-1320BNF	6/15/2005	V1008453	S987481	46162	N001	02000069
AR-1322-752SF	1/20/2003	IV518344	S492254	35093	N001	02000211
AR-1322BNF	1/14/2003	IV516136	S499131	34472	N001	02000069
AR-1322SXF	9/11/2002	IV464295	S446283	32537	N001	02005300
AR-1324BF	8/20/2002	IV455926	S437841	32710	N001	02000076
AR-1324BF-2	1/20/2003	IV518381	S501012	34823	N001	02001608
AR-1324BNF	4/4/2005	IV959968	S938633	59550	N001	02000818
AR-1324HF	11/11/2003	IV662430	S642145	35468	N001	02003274
AR-1324SF	8/20/2002	IV455869	S437761	32539	N001	02000069
AR-13920DS	10/28/2003	IV654770	S634416	3191	N001	02000071
AR-13930DS	9/15/2003	IV631086	G611151	3231	N001	02000244
AR-1902SF	9/4/2003	IV627239	G607224	37967	N001	02000244
AR-1915SF	11/19/2002	IV492083	G474703	659-5	N001	02000244
AR-1915SNF	5/24/2005	IV993636	S972644	56817	N001	02011109
AR-1920BF	12/23/2002	IV507362	S490302	31415	N001	02011482
AR-1920BF-37	4/26/2005	IV974560	B953813	42012	D010	02013820
AR-1920BFT	2/24/2004	IV720917	S698914	35798	N001	02000069
AR-1920BNF	10/23/2003	IV651950	S631500	34340	N001	02004001
AR-1920BNP	9/9/2004	IV831261	S807832	39067	N001	02008052
AR-1920BT	10/8/2004	IV848270	S825641	39678	N001	02000069
AR-1920SF	4/28/2003	IV566518	G548621	35629	N001	02000244
AR-1920SFT	3/5/2004	IV728452	S706077	36424A	N001	02017573
AR-1920SNF	12/30/2004	IV898169	S875373	55500	N001	02009982
AR-1925BF	2/3/2003	IV525235	S508502	31907	N001	02007888
AR-1925BFSP	8/4/2004	IV813215	G789524	39068	N001	02000244
AR-1925BNF	11/17/2003	IV664939	G644573	35195	N001	02000244
AR-1925BNP	9/9/2004	IV831261	S807832	39069	N001	02008052
AR-1925SF	8/13/2003	IV617604	S597769	37934	N001	02002045
AR-1927BF	2/1/2005	IV918263	S897258	63001	N001	02000069
AR-1927BNF	4/25/2005	IV973180	S952251	64852	N001	02000520
AR-1928SF	5/6/2003	IV570976	S552984	36234	N001	02000009
AR-1928SF-2	4/14/2005	IV967540	S946680	66432	N001	02008281
AR-1928SNF	6/28/2004	IV793431	B769413	41010	D034	02001327
AR-1928SNF-2	Not Produced yet. - Scheduled for availability 9/05					
ar-1929	5/7/2002	IV398855	G380959	2021402	N001	02000244
AR-1934BF	8/20/2002	IV455709	S437535	32531	N001	02003672
AR-1934BF-2	1/20/2003	IV518470	S501400	34908	N001	02009797
AR-1934BFT	7/23/2004	IV806979	G783100	42323	N001	02000244
AR-1934BFX	9/15/2004	IV834896	S811648	42138	N001	02003274
AR-1934BNF	3/16/2005	IV947032	S925466	59560	N001	02012414
AR-2225S	8/11/2003	IV616483	S596712	37414	N001	02001545
AR-2226S	6/23/2004	IV791766	S767483	41871	N001	02003274
AR-4066L	9/17/2004	IV836301	S813178	42480	N001	02006240
AR-4066R	9/17/2004	IV836301	S813178	42482	N001	02006240
AR-4066ST	9/2/2004	IV828628	B805591	42481	D018	02000073
AR-7200	8/9/2001	IV313540	S296368	405	N001	02003274
AR-7201	10/16/2002	IV477656	G459699	654	N001	02000244
AR-7202	7/29/2002	IV447210	G428977	606	N001	02000244
AR-7203	4/3/2003	IV555999	S538522	736	N001	02002405
AR-7204	3/27/2003	IV551840	S523005	827	N001	02014245
AR-7205	2/17/2004	IV716340	G694839	957	N001	02000244
AR-7205T	2/6/2004	IV710484	S689254	958	N001	02008201
AR-7207	4/2/2004	IV745937	S722606	1098	N001	02000069
AR-7208	Just released. No sales yet.					
AR-7209	10/21/2002	IV479871	S462169	673	N001	02009982
AR-7209SN	5/24/2004	IV775366	S750821	1026	N001	02009982
ar-7209t	7/29/2003	IV398855	G380959	886	N001	02000244
AR-7210	2/18/2002	IV382655	S364586	557	N001	02008052
AR-7211	11/1/2002	IV485141	G467458	605	N001	02000244
AR-7219	1/27/2004	IV703787	G681676	878	N001	02000244
AR-7219	1/27/2004	IV703787	G681676	878	N001	02000244
AR-7220	1/16/2003	IV517123	S500083	607	N001	02003908
AR-7221	1/16/2003	IV517018	G500040	681	N001	02000244
AR-7222	12/30/2003	IV688721	G668074	906	N001	02000244
AR-7223	11/17/2004	IV871562	S849761	3198	N001	02000069
AR-7224	7/9/2004	IV799942	S775938	1254	N001	02003079
AR-7225	5/1/2003	IV568975	G551049	732	N001	02000244
AR-7227-01	6/3/2004	IV781308	S756864	1147	N001	02016766
AR-7227-02	6/2/2004	IV780119	S755625	1149	N001	02014201
AR-7228	4/17/2003	IV561837	G544236	733	N001	02000244
AR-7229-12	4/12/2004	IV750637	S727106	1036	N001	02000076
AR-7229-20	4/12/2004	IV750637	S727106	1038	N001	02000076
AR-7230-01	5/19/2004	IV772818	S748209	1118	N001	02012346
AR-7230-02	6/24/2004	IV792330	S767941	1119	N001	02002405
AR-7232-01	5/24/2005	IV992613	B972252	1555	D036	02000094
AR-7232-02	No Sales yet - Just Released					
AR-7232-03	No Sales - 1st receipt late July 2005					
AR-7237	4/21/2004	IV755806	M732611	1094	N001	02003274
AR-7250	5/10/2005	IV984667	S963999	1426	N001	02000076
AR-7251	No Sales yet - Just Released					
AR-8920DS	8/18/2004	IV398855	G380959	1247	N001	02000244
AR-8921DS	8/18/2004	IV398855	G380959	1248	N001	02000244

"CONFIDENTIAL-
OUTSIDE ATTORNEYS'
EYES ONLY"

ARM 24165-A

EXHIBIT 28

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,
6 A Massachusetts Corporation,
7 Plaintiff,

8 vs.

9 ARTHREX, INC.,
10 A Delaware Corporation,
11 Defendants.

12 _____ x

13 CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

14 DAY 1 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 26, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

ORIGINAL

	Page 54
1 of the question.	08:59:18a
2 THE WITNESS: I have no --	08:59:19a
3 BY MR. SABER:	08:59:20a
4 Q. Is it PET?	08:59:20a
5 A. PET and polyester are used	08:59:21a
6 interchangeably, yes. The polyethylene	08:59:23a
7 terephthlate is the official chemical name for	08:59:28a
8 polyester. Polyester is essentially a shorthand	08:59:32a
9 way of referring to polyethylene terephthlate.	08:59:36a
10 Q. Okay.	08:59:40a
11 A. Whenever you see those terms, they're	08:59:41a
12 the same thing.	08:59:42a
13 Q. Polyester, or...?	08:59:43a
14 A. Polyester and polyethylene	08:59:43a
15 terephthlate, T-E-R-E-P-T-H-L-A-T-E, and polyester	08:59:51a
16 are used interchangeably, in the literature, in	09:00:00a
17 the science, in teaching, by everybody.	09:00:03a
18 Q. Okay. And poly -- I have a little	09:00:09a
19 trouble with this --	09:00:12a
20 A. Okay.	09:00:15a
21 Q. -- polyethylene terephthlate --	09:00:15a
22 A. Terephthlate.	09:00:16a
23 Q. -- is referred to as PET?	09:00:16a
24 A. That is correct.	09:00:17a
25 Q. The -- could you -- I just want to tie	09:00:19a

	Page 165
1 about sutures, but actually designing and	11:16:23a
2 developing and the quality associated with that	11:16:25a
3 was for U.S. Surgical; I don't recall if we	11:16:32a
4 coated or not.	11:16:34a
5 Q. You just don't remember from that	11:16:35a
6 project?	11:16:38a
7 A. Right.	11:16:38a
8 Q. Do you recall whether you've had any	11:16:38a
9 experience with respect to coating of sutures in	11:16:40a
10 your background prior to your work on this case?	11:16:44a
11 A. I don't recall, because, you know, we	11:16:49a
12 looked at the vascular prosthesis patent that had	11:16:51a
13 sutures on it, I don't recall if they were coated	11:16:53a
14 or not. I don't know.	11:16:56a
15 Q. Have you -- do you recall whether you	11:16:58a
16 have had any experience with respect to what	11:17:01a
17 coating -- how coating impacts on suture	11:17:08a
18 properties?	11:17:11a
19 A. Well, I've looked at the Gitis report	11:17:15a
20 and tried to --	11:17:19a
21 Q. I'm sorry, prior to your work in this	11:17:20a
22 case.	11:17:21a
23 A. Not prior to the work in this case.	11:17:22a
24 Q. Okay. The -- would it be correct to	11:17:23a
25 say that what you've learned about coating and	11:17:31a

	Page 166
1 its impact on suture properties is in conjunction	11:17:33a
2 with your work on this case?	11:17:35a
3 A. That would be proper to say that, yes.	11:17:38a
4 Q. The -- do you have an opinion as to	11:17:44a
5 whether it is generally well-known in the suture	11:17:45a
6 art that coating multifilament suture improves	11:17:48a
7 the tactile smoothless -- smoothness, pliability,	11:17:53a
8 and knot tie-down performance of that suture?	11:17:58a
9 A. That's a long question. Do that --	11:18:02a
10 let's do that slower and --	11:18:05a
11 Q. Sure, I'll even try to take it into	11:18:06a
12 parts.	11:18:09a
13 A. Yeah.	11:18:09a
14 Q. Do you have an opinion -- well, let me	11:18:09a
15 ask you this. Is it correct that it is generally	11:18:12a
16 known in the suture art that coating a	11:18:14a
17 multifilament suture improves the tactile	11:18:16a
18 smoothness of the suture?	11:18:18a
19 MR. BONELLA: Objection; incomplete	11:18:22a
20 hypothetical.	11:18:23a
21 THE WITNESS: I haven't seen	11:18:24a
22 anything that says that.	11:18:25a
23 BY MR. SABER:	11:18:26a
24 Q. You don't have an opinion one way or	11:18:26a
25 the other?	11:18:28a

		Page 167
1	A. I have no opinion on that.	11:18:28a
2	Q. Do you know whether it is generally	11:18:29a
3	known in the suture art that coating a	11:18:31a
4	multifilament suture improves the pliability of	11:18:35a
5	that suture?	11:18:39a
6	MR. BONELLA: Objection; incomplete	11:18:40a
7	hypothetical.	11:18:41a
8	THE WITNESS: Yeah, I've seen	11:18:42a
9	nothing like that. I can't judge that.	11:18:43a
10	BY MR. SABER:	11:18:45a
11	Q. You have no opinion one way or the	11:18:45a
12	other?	11:18:47a
13	A. I have an opinion that coating only	11:18:47a
14	affects in a minor way the handleability.	11:18:49a
15	Q. Okay.	11:18:52a
16	A. That's it.	11:18:52a
17	Q. Okay. Well, let me -- what do you	11:18:52a
18	mean when you say handleability?	11:18:55a
19	A. You know, if the guy does this	11:18:56a
20	(indicating) and says it feels smooth, then	11:18:58a
21	that's all. And even that from what I've read in	11:19:00a
22	some of your experts' reports, like Burks', even	11:19:06a
23	that is almost imperceptible.	11:19:09a
24	Q. Is it -- do you agree that it is	11:19:16a
25	generally known in the suture art that coating a	11:19:20a

	Page 168
1 multifilament suture improves the knot tie-down	11:19:22a
2 performance of that suture?	11:19:25a
3 MR. BONELLA: Objection; incomplete	11:19:27a
4 hypothetical.	11:19:29a
5 THE WITNESS: I've seen no	11:19:29a
6 evidence where that's discussed.	11:19:31a
7 BY MR. SABER:	11:19:33a
8 Q. So you don't have an opinion one way	11:19:33a
9 or the other?	11:19:37a
10 MR. BONELLA: Objection;	11:19:37a
11 incomplete --	11:19:38a
12 BY MR. SABER:	11:19:39a
13 Q. Is that correct?	11:19:39a
14 MR. BONELLA: Incomplete	11:19:40a
15 hypothetical on that previous question.	11:19:41a
16 THE WITNESS: My opinion is	11:19:43a
17 that coating only has an immaterial effect that	11:19:43a
18 might -- might -- affect handleability, and	11:19:47a
19 that's all.	11:19:51a
20 BY MR. SABER:	11:19:51a
21 Q. What is that opinion based on?	11:19:51a
22 A. It's based mostly on some of the work	11:19:53a
23 I've read from Gitis. It's an opinion of looking	11:19:55a
24 at the micrographs that I took and seeing the	11:19:59a
25 level of coating that was on those sutures. It's	11:20:02a

	Page 169
1 a -- it's based on some theoretical calculations	11:20:06a
2 I made associated with bending rigidity. It's	11:20:12a
3 understanding how tensile properties of fibers	11:20:17a
4 relate to the tensile properties of the braided	11:20:21a
5 structure. In no case can you show that coating	11:20:24a
6 does anything of any material. It's almost an	11:20:27a
7 afterthought to put it on.	11:20:31a
8 I think the patent even says, you	11:20:45a
9 know, in some cases it's expensive, don't even	11:20:46a
10 bother with it, it's not that a big deal. It's	11:20:51a
11 expensive and don't even put it on it.	11:20:54a
12 Q. Just give me a moment.	11:20:57a
13 A. I just want to read from the patent.	11:21:09a
14 MR. BONELLA: Why don't you wait	11:21:12a
15 until there's a question.	11:21:13a
16 THE WITNESS: Okay. Okay. Okay.	11:21:14a
17 MR. BONELLA: There's no question.	11:21:15a
18 (Whereupon a document was	11:21:32a
19 marked, for identification purposes, as	11:21:32a
20 Defendant's Exhibit-202.)	11:21:33a
21 THE VIDEOGRAPHER: Going off the	11:21:54a
22 video record.	11:21:55a
23 (A discussion was held off the	11:22:15a
24 record from 11:21 AM to 11:22 AM, with the video	11:22:15a
25 record then resuming.)	11:22:20a

Page 211

1 from the second set, and the dissimilar yarns 12:02:23p

2 have at least some different properties that 12:02:28p

3 contribute to the overall properties of the 12:02:31p

4 braid. That is what I've been asked to assume. 12:02:31p

5 That is what my opinions are based on, those 12:02:33p

6 basic and novel characteristics. 12:02:36p

7 Q. In your opinion, sir, if the coating 12:02:38p

8 improves one of the properties that one of the 12:02:40p

9 materials contributes to the braid, can it have a 12:02:42p

10 -- can it materially affect the basic and novel 12:02:45p

11 characteristics of the invention? 12:02:48p

12 A. Not under this definition, no. 12:02:50p

13 Q. Your answer is no? 12:02:51p

14 A. The answer is no. 12:02:52p

15 Q. Okay. 12:02:55p

16 MR. SABER: Mike, this is 12:02:55p

17 probably a pretty good time. 12:02:56p

18 MR. BONELLA: Okay. 12:03:00p

19 BY MR. SABER: 12:03:00p

20 Q. What's the basis for that opinion? 12:03:00p

21 A. The basis for what opinion? 12:03:01p

22 Q. What you just said, that even if it 12:03:02p

23 improves the property that one of the yarns adds, 12:03:05p

24 it cannot affect the basic and novel 12:03:10p

25 characteristics. 12:03:12p

		Page 276 02:29:00p
1	equivalents?	
2	A. Okay. Let me -- let me go through my	02:29:05p
3	report.	02:29:07p
4	First we look at each -- you make	02:29:07p
5	a table and we look at each claim or claim	02:29:10p
6	element and we see what that claim element or	02:29:13p
7	claim is claiming.	02:29:17p
8	Then we look under the function	02:29:18p
9	of the claim limitation. Okay? We see what it	02:29:21p
10	-- what is it -- what is the function of this, we	02:29:25p
11	make a determination what the function is, and	02:29:26p
12	then we compare it to what the function is of the	02:29:28p
13	material that's in question and we match the	02:29:31p
14	functions. Okay?	02:29:33p
15	Then we see -- once we've	02:29:34p
16	determined what the function is, we see the way	02:29:37p
17	that it met that function. And after that, we	02:29:40p
18	see what the final results are.	02:29:43p
19	So we're always -- we take the	02:29:43p
20	claim. Okay? We decide what the function,	02:29:45p
21	way or result is that we're trying to achieve,	02:29:49p
22	and then we look at the material in question	02:29:51p
23	and see if it meets the function, way and	02:29:53p
24	result for it to be an insubstantial	02:29:56p
25	difference.	02:29:58p

	Page 279
1 yarn from the second set.	02:33:10p
2 A. Right.	02:33:13p
3 Q. Correct?	02:33:13p
4 A. Right.	02:33:14p
5 Q. Now, was that your opinion or was that	02:33:14p
6 the function -- was that function given to you by	02:33:16p
7 the attorneys?	02:33:19p
8 A. No, it was the function that I got	02:33:19p
9 from the '446 patent. It says, My opinion	02:33:21p
10 regarding the function of the first fiber	02:33:25p
11 material is supported by the '446.	02:33:27p
12 Q. No --	02:33:29p
13 A. Let me --	02:33:30p
14 Q. I just want you to answer my	02:33:31p
15 question. I mean, was this -- I'm just trying to	02:33:33p
16 find out does this -- are you the one who came up	02:33:36p
17 with the function, or was that something that was	02:33:39p
18 an assumption that was given to you by the	02:33:40p
19 attorneys?	02:33:43p
20 MR. BONELLA: Objection. Asked	02:33:43p
21 and answered.	02:33:44p
22 BY MR. SABER:	02:33:44p
23 Q. That's my question.	02:33:44p
24 A. Mr. Falke explained to me how the	02:33:47p
25 function/way result works from a legal	02:33:50p

		Page 285
1	Q. The first thing you say is Column 2,	02:40:06p
2	Lines 50 to 52, in the patent?	02:40:08p
3	A. Yes.	02:40:11p
4	Q. And this is Exhibit D?	02:40:11p
5	A. Yes, sir.	02:40:14p
6	Q. And that's the sentence that begins,	02:40:14p
7	Surprisingly --	02:40:16p
8	A. Yes.	02:40:17p
9	Q. -- the heterogeneous braids may	02:40:17p
10	exhibit -- well, tell me specifically what in	02:40:19p
11	that, because I know the numbers get a little bit	02:40:22p
12	off, as we know.	02:40:24p
13	A. I understand.	02:40:25p
14	Q. Tell me specifically what you're	02:40:26p
15	referring to at Column 2, Lines 50 to 52.	02:40:27p
16	A. Well, I also have it in my -- in my	02:40:31p
17	report, the -- I quoted, The patent explains that	02:40:35p
18	the first fiber-forming material is dissimilar to	02:40:38p
19	the second set -- second fiber, and the braid of	02:40:41p
20	the similar yarns provides, quote, from the	02:40:46p
21	patent outstanding properties attributable to the	02:40:49p
22	specific properties of the dissimilar	02:40:52p
23	fiber-forming materials which make up the braided	02:40:55p
24	yarns.	02:40:57p
25	Q. Yeah, I want -- I just want to know	02:41:00p

	Page 289
1 never looked at it.	02:44:16p
2 Q. Okay. Did you -- do you have any	02:44:16p
3 understanding of what the claims of the '446	02:44:19p
4 patent were as the patent application was	02:44:21p
5 originally filed?	02:44:26p
6 A. No.	02:44:27p
7 Q. Have you studied as to whether there	02:44:28p
8 were any amendments to the claims --	02:44:31p
9 A. No.	02:44:33p
10 Q. -- in the prosecution history?	02:44:33p
11 A. No.	02:44:35p
12 Q. Okay. Do you think that understanding	02:44:35p
13 the prosecution history in any amendments to the	02:44:39p
14 claims is important for understanding the	02:44:43p
15 function of limitation A?	02:44:46p
16 A. Not in an infringement situation, no.	02:44:53p
17 Q. Okay. You would agree with me that	02:44:59p
18 limitation A that we're discussing requires that	02:45:06p
19 the material be one of the specified listed	02:45:12p
20 materials to literally meet that limitation,	02:45:16p
21 correct?	02:45:20p
22 A. To literally meet it?	02:45:20p
23 Q. Yes.	02:45:22p
24 A. Yes.	02:45:22p
25 Q. Okay. Now, let me refer your	02:45:27p

	Page 290
1 attention to Paragraph 56 of your report.	02:45:55p
2 MR. BONELLA: The first report.	02:46:00p
3 MR. SABER: Yes, we're in the	02:46:01p
4 first report.	02:46:02p
5 BY MR. SABER:	02:46:02p
6 Q. On Page 21.	02:46:02p
7 A. Okay.	02:46:03p
8 Q. And you refer to the testimony of	02:46:04p
9 Mr. Hallet in that paragraph?	02:46:11p
10 A. Yes. Excuse me. Yes.	02:46:13p
11 Q. I'm sorry.	02:46:15p
12 A. Sorry.	02:46:16p
13 Q. And you refer to the testimony of	02:46:17p
14 Mr. Hallet that in the development of FiberWire	02:46:21p
15 he had constructed a 100 percent homogeneous	02:46:25p
16 ultra high molecular weight PE braid but Arthrex	02:46:29p
17 had requested a less stiff braid?	02:46:32p
18 A. That's what I write, yes.	02:46:36p
19 Q. Okay. Why did you rely upon that	02:46:39p
20 testimony? Or let me just and then the next	02:46:40p
21 sentence is, Mr. Hallet then made a heterogeneous	02:46:45p
22 braid of ultra high molecular weight polyethylene	02:46:48p
23 and PET to get the strength of ultra high	02:46:50p
24 molecular weight PET and the flexibility of PET?	02:46:53p
25 A. Yes.	02:46:57p

		Page 300
1	A. PET has a lower tensile modulus and	02:56:30p
2	can affect the tensile stiffness -- I mean, the	02:56:33p
3	bending stiffness in a positive fashion.	02:56:36p
4	Q. Do you mean make it easier to bend?	02:56:39p
5	A. Easier to bend.	02:56:41p
6	Q. Right. And --	02:56:42p
7	A. And easier to hold a knot.	02:56:43p
8	Q. Am I correct that adding the PET to	02:56:46p
9	the ultra high molecular weight braid made the	02:56:51p
10	braid easier to bend?	02:56:55p
11	A. That's what people have said, yes.	02:56:58p
12	Q. Do you believe that to be true?	02:57:00p
13	A. I believe that because it has a lower	02:57:03p
14	tensile modulus, it could make it easier to bend,	02:57:07p
15	that's correct. Modulus, M-O-D-U-L-U-S.	02:57:12p
16	Q. Would you expect that adding the PET	02:57:15p
17	would make the braid easier to bend?	02:57:21p
18	A. Adding or substituting?	02:57:23p
19	Q. Adding -- well, going from an all	02:57:24p
20	ultra high molecular weight PE braid --	02:57:30p
21	A. Right.	02:57:33p
22	Q. -- to a heterogeneous braid of the	02:57:34p
23	combination of ultra high molecular weight PE and	02:57:37p
24	PET would make the braid easier to bend; is that	02:57:40p
25	what your expectation is?	02:57:45p

		Page 301
1	A. In the context of this invention or in	02:57:46p
2	general?	02:57:49p
3	Q. In the context of this invention.	02:57:49p
4	A. In the context of this invention, yes.	02:57:51p
5	Q. Okay. In the context of this	02:57:54p
6	invention, is it your opinion that the ultra high	02:57:55p
7	molecular weight PE braid alone was not easy to	02:58:00p
8	bend?	02:58:05p
9	A. That it was -- it was -- I'm going by	02:58:06p
10	what Mr. Hallet testified, he said Arthrex	02:58:12p
11	requested a less stiff braid, so he went to a	02:58:14p
12	combination, a tailored combination, yes.	02:58:16p
13	Q. So that and would that be your	02:58:18p
14	expectation?	02:58:20p
15	A. That's what I would do.	02:58:20p
16	Q. In the context of this invention?	02:58:21p
17	A. In the context of this invention.	02:58:23p
18	Q. You would expect that the ultra high	02:58:24p
19	molecular weight braid would be -- would not be	02:58:26p
20	easy to bend?	02:58:29p
21	A. Right.	02:58:30p
22	Q. Okay.	02:58:31p
23	A. And he solved the problem by going to	02:58:31p
24	what's the novel and basic characteristics of our	02:58:36p
25	invention. The '446, it's not mine.	02:58:43p

Deposition of:
Dr. David S. Brrokstein, Vol. II

July 27, 2006

Page 339

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS

4 _____ x

5 DePUY-MITEK, INC.,
6 A Massachusetts Corporation,
7 Plaintiff,

8 vs.

ORIGINAL

9 ARTHREX, INC.,
10 A Delaware Corporation,
11 Defendants.

12 _____ x

13

14 DAY 2 OF 2

15 DEPOSITION OF DR. DAVID S. BROOKSTEIN

16 Philadelphia, Pennsylvania

17 July 27, 2006

18

19

20 Reported by:

21

22 PAMELA HARRISON, RMR, CRR, CSR

23

24

25

1	A.	It is my opinion that if the coating	10:24:09a
2		in some miraculous way made those materials not	10:24:11a
3		yarns anymore and they were no -- they were not	10:24:15a
4		dissimilar anymore, that that would be a change.	10:24:17a
5		If all of a sudden what was once a set of two	10:24:22a
6		dissimilar yarns miraculously became, for	10:24:26a
7		instance, a monofilament, that would be a change,	10:24:29a
8		yeah.	10:24:31a
9	Q.	And that would affect the basic and	10:24:32a
10		novel characteristics?	10:24:33a
11	A.	If the basic and novel characteristics	10:24:34a
12		are two dissimilar yarns, yes, and all of a	10:24:35a
13		sudden there weren't yarns in there anymore, it	10:24:38a
14		was some new material that was -- that we don't	10:24:41a
15		know about.	10:24:43a
16	Q.	Or the yarns were the same yarns, made	10:24:44a
17		the yarns into the same yarns?	10:24:46a
18	A.	If they were not dissimilar, right.	10:24:48a
19	Q.	Right. So is it your opinion that if	10:24:49a
20		the coating does not -- does not achieve the goal	10:24:54a
21		that you just described, then it does not affect	10:25:00a
22		the basic and novel characteristics of the	10:25:02a
23		invention as Dr. Mukherjee defines it?	10:25:05a
24	A.	Can you repeat the question.	10:25:07a
25	Q.	Yeah, let me try and rephrase it.	10:25:08a

		Page 400
1	Is it your opinion that the	10:25:12a
2	coating -- if the coating does not transform	10:25:15a
3	the braided material into another structure,	10:25:20a
4	would you -- let me ask it this way. What do	10:25:24a
5	you mean when you say transform the braided	10:25:27a
6	FiberWire materials into another structure?	10:25:30a
7	A. What do I mean?	10:25:32a
8	Q. Yes.	10:25:33a
9	A. I mean it's not dissimilar yarns	10:25:34a
10	anymore, that would be an example of what I	10:25:36a
11	mean. That all of a sudden you had a set from A,	10:25:38a
12	a set from B and now it was some magical	10:25:41a
13	structure that wasn't yarns, it wasn't two sets,	10:25:45a
14	they were all the same, that would be a	10:25:48a
15	transformation.	10:25:50a
16	Q. Okay.	10:25:52a
17	A. It would be alchemy, but it would be a	10:25:52a
18	transformation.	10:25:56a
19	Q. Okay. If that transformation doesn't	10:25:56a
20	occur by the coating, then is it your opinion	10:25:58a
21	that the coating doesn't affect the basic and	10:26:01a
22	novel characteristics of the invention?	10:26:02a
23	MR. BONELLA: Objection.	10:26:04a
24	THE WITNESS: That's not what I	10:26:04a
25	said.	10:26:05a

EXHIBIT 29

ETHICON, INC.
a Johnson & Johnson company

WOUND CLOSURE MANUAL

procedure, and the type of tissue involved, the surgeon will select suture material that will retain its strength until the wound heals sufficiently to withstand stress on its own.

SUTURE CHARACTERISTICS

The choice of suture materials generally depends on whether the wound closure occurs in one or more layers. In selecting the most appropriate sutures, the surgeon takes into account the amount of tension on the wound, the number of layers of closure, depth of suture placement, anticipated amount of edema, and anticipated timing of suture removal.

Optimal suture qualities include:

1. High uniform tensile strength, permitting use of finer sizes.
2. High tensile strength retention *in vivo*, holding the wound securely throughout the critical healing period, followed by rapid absorption.
3. Consistent uniform diameter.
4. Sterile.
5. Pliable for ease of handling and knot security.
6. Freedom from irritating substances or impurities for optimum tissue acceptance.
7. Predictable performance.

SIZE AND TENSILE STRENGTH

Size denotes the diameter of the suture material. The accepted surgical practice is to use the smallest diameter suture that will adequately hold the mending wounded tissue. This practice minimizes trauma as the suture is passed through the tissue to effect closure. It also ensures that the minimum mass of foreign material is left in the body. Suture size is stated numerically; as the number of 0s in the suture size increases, the diameter of the strand decreases. For example, size 5-0, or 00000, is smaller in diameter than size 4-0, or 0000. The smaller the size, the less tensile strength the suture will have.

Knot tensile strength is measured by the force, in pounds, which the suture strand can withstand before it breaks when knotted. The tensile strength of the tissue to be mended (its ability to withstand stress) determines the size and tensile strength of the suturing material the surgeon selects. The accepted rule is that the tensile strength of the suture need never exceed the tensile strength of the tissue. However, sutures should be at least as strong as normal tissue through which they are being placed.

MONOFILAMENT VS. MULTIFILAMENT STRANDS

Sutures are classified according to the number of strands of which they are comprised. *Monofilament sutures* are made of a single strand of material. Because of their simplified structure, they encounter less resistance as they pass through tissue than multifilament suture material. They also resist harboring organisms which may cause infection.

These characteristics make monofilament sutures well-suited to vascular surgery. Monofilament sutures tie down easily. However, because of their construction, extreme care must be taken when handling and tying these sutures. Crushing or crimping of this suture type can nick or create a weak spot in the strand. This may result in suture breakage.

Multifilament sutures consist of several filaments, or strands, twisted or braided together. This affords greater tensile strength, pliability, and flexibility. Multifilament sutures may also be coated to help them pass relatively smoothly through tissue and enhance handling characteristics.

Coated multifilament sutures are well-suited to intestinal procedures.

METRIC MEASURES AND U.S.P. SUTURE DIAMETER EQUIVALENTS

TABLE 1

U.S.P. Size	11-0	10-0	9-0	8-0	7-0	6-0	5-0	4-0	3-0	2-0	0	1	2	3	4	5	6
Natural Collagen	—	0.2	0.3	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	7.0	8.0	—	—
Synthetic Absorbables	—	0.2	0.3	0.4	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	6.0	7.0	—
Nonabsorbable Materials	0.1	0.2	0.3	0.4	0.5	0.7	1.0	1.5	2.0	3.0	3.5	4.0	5.0	6.0	6.0	7.0	8.0

* Trademark

ETHICON, INC.
a Johnson & Johnson company

WOUND HEALING

SUTURES

NEEDLES

ADHESIVES

SURGICAL MESH

TO VIEW THE E-CATALOG GO TO THE
HEALTHCARE PROFESSIONAL SECTION OF
WWW.ETHICON.COM

WOUND CLOSURE MANUAL

ETHICON, INC., PO BOX 151, SOMERVILLE, NJ 08876-0151

® TRADEMARK
™ ETHICON, INC.
© 2005, ETHICON, INC.

EXHIBIT 30

United States Patent [19][11] **Patent Number:** **4,532,929****Mattei et al.**[45] **Date of Patent:** **Aug. 6, 1985**[54] **DRY COATING OF SURGICAL FILAMENTS**

[56]

References Cited**U.S. PATENT DOCUMENTS**[75] **Inventors:** **Frank V. Mattei**, Piscataway; **Donald W. Regula**, Flagtown, both of N.J.

3,478,140	11/1969	Kronenthal et al.	128/335.5
4,027,676	6/1977	Mattei	128/335.5
4,047,533	9/1977	Perciaccante et al.	128/335.5
4,105,034	8/1978	Shalaby et al.	128/335.5
4,201,216	5/1980	Mattei	128/335.5

[73] **Assignee:** **Ethicon, Inc.**, Somerville, N.J.[21] **Appl. No.:** **633,759***Primary Examiner*—Jacqueline V. Howard*Attorney, Agent, or Firm*—Charles J. Metz[22] **Filed:** **Jul. 23, 1984**[57] **ABSTRACT**[51] **Int. Cl.³** **A61L 17/00**[52] **U.S. Cl.** **128/335.5; 427/2; 428/263; 428/378**[58] **Field of Search** **128/335, 335.5; 428/263, 378; 427/2**

Braided or monofilament surgical filaments are coated with dry, powdered, substantially water-insoluble, absorbable salt of a C₆ or higher fatty acid, such as calcium stearate.

20 Claims, No Drawings

4,532,929

1

DRY COATING OF SURGICAL FILAMENTS

TECHNICAL FIELD

This invention relates to a dry, absorbable composition useful as a coating and lubricating finish for surgical filaments, and to a method for using said composition. More particularly, this invention relates to a means for improving the tie-down properties of absorbable and non-absorbable monofilament surgical filaments as well as multifilament surgical filaments by coating them with a dry, absorbable lubricating composition.

BACKGROUND ART

Suture materials and other surgical filaments such as ligatures are generally classified as either absorbable or non-absorbable, with each type of suture material being preferred for certain applications. Absorbable suture materials are preferred for internal wound repair in which the sewn tissues will hold together without suture reinforcement after healing and in which a nonabsorbed suture may promote tissue irritation or other adverse bodily reaction over an extended period of time. Suture materials are considered to be absorbable if they disappear from the sewn tissue within about a year after surgery, but many absorbable suture materials disappear within shorter periods.

The earliest available absorbable suture materials were surgical gut and extruded collagenous materials. More recently, absorbable sutures derived from synthetic polymers have been developed which are strong, dimensionally uniform, and storage stable in the dry state. Typical of such polymers are lactide homopolymers and copolymers of lactide and glycolide such as those disclosed in U.S. Pat. No. 3,636,956, and glycolide homopolymers such as those disclosed in U.S. Pat. No. 3,565,869.

Monofilament synthetic absorbable suture materials are generally stiffer than their multifilament surgical gut or collagen counterparts, and synthetic absorbable sutures are therefore usually employed in a multifilament, braided construction in order to provide the suture with the desired degree of softness and flexibility. Such multifilament sutures exhibit a certain degree of undesirable roughness or "grabbiness" in what has been termed their "tie-down" performance, i.e., the ease or difficulty of sliding a knot down the suture into place, or the ease of snugging a square knot in place.

Multifilament nonabsorbable sutures such as braided sutures of polyethylene terephthalate, for example, can be improved with respect to tie-down performance by coating the external surface of the suture with solid particles of polytetrafluoroethylene and a binder resin as disclosed in U.S. Pat. No. 3,527,650. This procedure, however, is undesirable as applied to absorbable sutures because polytetrafluoroethylene is nonabsorbable and sutures coated therewith would leave a polymer residue in the sewn tissue, after the suture had been absorbed.

Multifilament, nonabsorbable sutures can also be improved with respect to tie-down performance by coating them with a linear polyester having a molecular weight between about 1,000 and about 15,000 and at least two carbon atoms between the ester linkages in the polymer chain as disclosed in U.S. Pat. No. 3,942,532.

U.S. Pat. No. 3,297,033 discloses that the synthetic absorbable sutures described therein may be coated with conventional suture coating materials such as a silicone or beeswax in order to modify the handling or

2

absorption rate of the sutures. These coating materials are not readily absorbable, however, and will accordingly leave an undesirable residue in the tissue after the suture itself is absorbed.

Many other compounds have been proposed as treating agents to improve the lubricity and handling of both natural and synthetic filaments. U.S. Pat. No. 3,896,841 describes the treatment of collagen sutures with a hygroscopic agent and lubricant to provide a suture which permanently retains at least 10 percent by weight moisture. Sutures so treated are reported to have increased suppleness and reduced drag when passing through tissue. Fatty compounds and derivatives of fatty compounds are suggested as useful lubricating agents for such collagen sutures.

U.S. Pat. No. 3,982,543 discloses that multifilament, absorbable sutures may be lubricated/coated with a copolymer of lactide and glycolide in order to reduce the capillarity of the suture, and that sutures so treated are reported to have improved run down.

Because of the nature of surgical procedures, sutures and ligatures are generally exposed to body fluids or passes one or more times through moist tissue before tying, and an effective suture coating composition ideally provides wet tie-down characteristics substantially equivalent to those of the dry suture.

U.S. Pat. No. 4,143,423 discloses coating surgical applicances with a gloving agent or lubricant comprising a water soluble nontoxic alkali metal compound such as sodium bicarbonate. The compound may be coated as a powder by dusting or from an aqueous solution. Water soluble compounds would not, however, be suitable as lubricants for surgical sutures due to the nature of surgical procedures. Thus, the lubricant powders would be dissolved prematurely.

U.S. Pat. No. 4,201,216, issued May 6, 1980, to Frank V. Mattei, discloses as a coating for sutures, particularly synthetic absorbable multifilament sutures, an absorbable composition comprising a film-forming polymer and a substantially water-insoluble salt of a C₆ or a higher fatty acid. The coating is preferably applied to the suture from a solvent solution to provide a final coating add-on of from about 2 to 10 percent by weight of the sutures. In accordance with the teachings of said U.S. Pat. No. 4,201,216, the film-forming polymer is preferably a copolymer of lactide and glycolide, while the fatty acid salt is preferably a calcium salt of a C₆ to C₂₂ fatty acid. The ratio of polymer to fatty acid salt in the coating composition may be within the range of about 1:4 to 4:1 parts by weight. The coating is wholly absorbable and is particularly useful for improving the dry and wet tie-down smoothness of braided sutures prepared from homopolymers and copolymers of lactide and glycolide, and other absorbable polymers. The patent discloses that where the compositions of the suture and the film former are identical, and in other instances where the suture material may be subject to some surface dissolution and/or surface swelling or softening by reason of the action of the film former solvent thereon, there may be a gradual transition between the substrate composition and the coating composition rather than a sharp interface between them. There may also be some weakening of the suture accompanying the application of such coating compositions.

It is an object of this invention to provide an improved method for coating monofilament sutures, as

well as multi-filament sutures of braided, twisted or covered construction, with a coating that improves the tie-down properties of such monofilament or multifilament sutures. It is a further object of this invention to provide a wholly absorbable coated synthetic monofilament or multifilament suture having improved and substantially equal dry and wet knot tie-down properties. It is yet a further object of this invention to provide such a wholly absorbable coated synthetic monofilament or multifilament suture having improved tie-down properties at least as desirable as those of sutures prepared in accordance with the teaching of U.S. Pat. No. 4,201,216, but having a substantially lower coating weight than that of the sutures of said U.S. Pat. No. 4,201,216, thus tie-down is improved by the minimal application of a safe material, such application being accomplished without using any organic solvents. The appearance and other esthetic attributes of the suture are only minimally affected, if at all, by the low level of add-on of the dry lubricating composition of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the invention, there is provided as a coating for surgical filaments such as sutures, and ligatures, particularly synthetic absorbable monofilament surgical filaments, an absorbable composition comprising a dry, finely powdered, substantially water insoluble salt of a C₆ or higher fatty acid. The coating may be applied on continuous lengths of monofilament or braid, using a series of powdered soft brushes followed by clean, soft wiping brushes to remove excess coating powder, or using other powder coating techniques that are known to the art, to provide a final coating add-on of below about 0.25 percent, and preferably below about 0.15 percent, by weight of the filament. The coating may also be applied to the filament manually by pulling the filament through fingers that had been powdered with the coating salt, e.g., calcium stearate, followed by pulling several times through clean fingers to remove any visible signs of the coating powder.

The fatty acid salt is preferably a calcium salt of a C₆ to C₂₂ fatty acid. The coating is particularly useful for improving the dry and wet tie-down smoothness of monofilament sutures, such as those prepared from homopolymers and copolymers of p-dioxanone, polyolefins such as polypropylene, certain polyesters, and the like, as well as braided sutures prepared from homopolymers and copolymers of lactide or glycolide and other absorbable polymers, polyethylene terephthalate, silk, and the like.

The fatty acid salts useful in the coating powder compositions of the invention include the calcium, magnesium, barium, aluminum, and zinc salts of C₆ and higher fatty acids, particularly those having from about 12 to 22 carbon atoms, and mixtures thereof. The calcium salts of stearic, palmitic and oleic acids are particularly preferred for use in the invention. Mixtures of these salts may offer advantages in certain applications.

The amount of coating composition applied to the suture, or the coating add-on, will vary depending upon the construction of the suture, e.g., the number of filaments and tightness of braid or twist. In general, the coating composition applied to a suture will constitute up to about 0.25 percent by weight of the coated suture, and preferably up to about 0.15 percent by weight of the

suture. As a practical matter, and for reasons of economy and general performance, it is generally preferred to apply the minimum amount of coating composition consistent with good tie-down performance, and this level of add-on is readily determined experimentally for any particular suture-coating system. Usually, the add-on will be at least about 0.02 weight percent, based on suture weight.

The improvement in tie-down properties imparted to sutures and ligatures may be determined semiquantitatively and subjectively by comparing the tie-down smoothness of coated and uncoated filaments during the act of tying down a single throw knot. Such comparisons are preferably made on both wet and dry filaments since many filament materials have different tie-down properties when tested wet or dry. Tie-down roughness is graded from 0 to 10, with 0 being comparable to a rough filament and 10 indicating no detectable roughness.

Tie-down properties are evaluated dry after the strands of suture or ligature have been conditioned for at least 2 days in a vacuum drying oven at room temperature and 100 microns absolute pressure, and wet after being immersed in water at 25° C. for 1 minute. Values above 4 are considered acceptable, while values of 7 or higher are comparable to conventional silicone coated silk and are considered fully satisfactory.

The tie-down roughness test is carried out as follows:

The calibration standards for the test are uncoated poly(glycolide-co-lactide) braid, size 2/0, which is arbitrarily assigned a 0 rating, and size 2/0 braided poly(ethylene terephthalate) having a coating of polytetrafluoroethylene, which is assigned a 10 rating. A 24-36 inch strand of the material being tested is looped under a stationary bar, and a single throw knot (overhand knot) is formed between the two free ends, near the ends. The two ends are grasped firmly in the hands and the ends are arranged so that the knot has its loops evenly spread out. Using 1-2 pounds of tension, the knot is caused to slide down at a moderate rate, with an even pull, until it comes to rest on the bar. After calibrating the strands for some 10-15 minutes with the two standards, the smoothness of tie-down is judged for the test samples, using the 0-10 scale. Usually, some 3-5 tie-downs are done on each strand, and about 4 strands are done per sample. For wet tie-down, the test is carried out immediately upon removal from the water. Only about 3 to 4 wet tie-downs are done on each strand, since the strand begins to dry out immediately upon removal from the water, and after 3 or 4 tests, is no longer wet. An average is taken of all the evaluations. While the test is subjective, and obviously operator-dependent, experiences has shown that different persons carrying out the test will get about the same results (i.e., the trends and differences between samples will be the same), even though the specific numbers obtained may not be exactly the same.

The following examples are provided to further illustrate and demonstrate the method and product of the invention. Unless otherwise stated, all parts and percentages are by weight.

EXAMPLE 1

Dry, powdered (100 percent smaller than 21 microns, 50 percent smaller than 8.5 microns) calcium stearate (in the form of a commercial food grade product consisting of about $\frac{1}{3}$ C₁₆ and $\frac{2}{3}$ C₁₈ fatty acid, with small amounts of C₁₄ and C₂₂ fatty acids) was applied as follows to size

4,532,929

5

1 dyed poly-p-dioxanone monofilament which had been scoured in acetone for three hours and then dried. The operator's fingers were powdered with the calcium stearate and the strands then individually pulled through the fingers 4-8 times so as to obtain a thorough and intimate coating. After removing the stearate from the fingers, the strands were pulled through clean fingers several more times to remove any visible signs of stearate.

EXAMPLE 2

The foregoing procedure was repeated using the monofilaments and fatty acid salt coating powders identified in Table I. The tie-down properties of the strands were then evaluated using the heretofore described semi-quantitative smoothness-of-tie-down tests, with the results set forth in Table I. The sterilized samples were sterilized either by ethylene oxide (EO) or by gamma irradiation from a cobalt-60 source.

TABLE I

Monofilament	% Add-on, 10 six foot strands	Smoothness of Tie-Down Ratings Based on 0-10 Subjective Scale					
		Dry			Wet		
		Unsterilized/Sterilized			Unsterilized/Sterilized		
Size 0, dyed poly-p-dioxanone monofilament	Uncoated control	3.5	4	(EO)	7.5	7.5	(EO)
Size 0, dyed poly-p-dioxanone monofilament	Calcium stearate	0.041	10	10	"	10	10
Size 0, dyed poly-p-dioxanone monofilament	Calcium palmitate		10	9.5	"	9.5	9.5
Size 0, dyed poly-p-dioxanone monofilament	Calcium laurate		10	10	"	10	10
Size 0, dyed poly-p-dioxanone monofilament	Calcium oleate		3	3	"	8	8
Size 0, dyed poly-p-dioxanone monofilament	Calcium undecylenate		10	10	"	9.5	9.5
Size 0, dyed poly-p-dioxanone monofilament	Zinc stearate	0.15	9	9.5	"	9.5	9
Size 0, dyed poly-p-dioxanone monofilament	Magnesium stearate		10	10	"	9	9.5
Size 0, dyed poly-p-dioxanone monofilament	Magnesium myristate		9.5	9.5	"	9.5	9.5
Size 0, dyed poly-p-dioxanone monofilament	Zinc undecylate		10	10	"	9.5	10
Size 0, dyed poly[tetramethylene terephthalate-CO-(2-octadecenyl) succinate] monofilament (U.S. Pat. No. 4,388,296)	Uncoated control		2	1.5	(COBALT)	2	2
	Calcium stearate		9	8	"	9	9
	Calcium palmitate		8	8	"	9	8.5
	Calcium laurate		6	5.5	"	2.5	4
	Zinc stearate		8.5	8.5	"	8.5	9
Size 0 Dyed Polypropylene monofilament	Uncoated control		2	1.5	(EO)	2	2
Size 0 Dyed Polypropylene monofilament	Calcium stearate	0.06	9	9	"	9.5	9.5
Size 0 Dyed Polypropylene monofilament	Calcium palmitate		9	9	"	9	9
Size 0 Dyed Polypropylene monofilament	Calcium laurate		9.5	9.5	"	9.5	9
Size 0 Dyed Polypropylene monofilament	Zinc stearate	0.126	9.5	9.5	"	9	9
Size 2/0 scoured nylon ⁽¹⁾ monofilament	Uncoated Control		6.5	—		7	—
	Calcium stearate	—	10	—		9.5	—

⁽¹⁾Soaked in acetone for 3 hours at room temperature.

As is apparent from the above results, the dry coating of the invention is effective for improving the tie-down characteristics of a variety of surgical filaments such as sutures and ligatures using various salts of fatty acids. In the tests reported in Table I, only the calcium oleate coating of the poly-(p-dioxanone) monofilament suture showed no improvement in the dry test. Even this suture showed slight improvement in the wet tie-down test, although the results were not as good as for the other salts.

6

It may be readily appreciated that the coating may be used with good results on absorbable monofilament and multifilament sutures and ligatures as well as on nonabsorbable monofilament and multifilament sutures and ligatures.

Nonabsorbable sutures and ligatures such as cotton, linen, silk, polypropylene, and polyester are sometimes coated with nonabsorbable compositions. Polyolefins are usually of monofilament construction while cotton, linen, silk, and polyester are usually of braided, twisted, or covered multifilament construction. While there is usually no requirement that coatings on such sutures be absorbable, the composition of the invention may, nevertheless, be used as a finish for nonabsorbable sutures if desired. The only suture material that has been tried and found not to be improved by the invention is unscoured nylon monofilament. That is because unscoured nylon already has such good tie-down properties that any improvement that might be imparted by the invention is

not detectable by the semi-quantitative subjective test used.

EXAMPLE 3

Twenty strands of size 0 undyed polyester (polyethylene terephthalate) braid, in three-foot lengths, were coated with dry calcium stearate powder by the procedure described in Example 1, above. The add-on level for the twenty strands was 1.5 weight percent (this was probably much higher than the add-on would be in a

4,532,929

7

commercial process, with a more efficient cleaning operation after the coating). Wet tie-down was $8\frac{1}{2}$ (average of 4 strands), while the dry tie-down was 9 (average of 4 strands), using the same test for smoothness of tie-down described above. The uncoated controls were rated at 1 for both dry and wet. The appearance of the coated strands was excellent; they appeared to the naked eye to be uncoated.

What is claimed is:

1. A synthetic surgical filament having improved and substantially equal dry and wet tie-down properties, said surgical filament having been coated with from about 0.02 to 0.25 percent by weight of a composition consisting essentially of a dry, powdered, substantially water-insoluble, absorbable salt of a C₆ or higher fatty acid.

2. A surgical filament of claim 1, wherein said higher fatty acid is selected from the group consisting of C₁₂ to C₂₂ fatty acids and mixtures thereof.

3. A surgical filament of claim 1, wherein the fatty acid salt is a salt of calcium, magnesium, barium, aluminum, or zinc.

4. A surgical filament of claim 2, wherein the fatty acid salt is a salt of calcium or magnesium.

5. A surgical filament of claim 4, wherein the fatty acid comprises a mixture of stearic and palmitic acid.

6. A surgical filament of claim 5, wherein the fatty acid salt comprises a mixture of calcium palmitate and calcium stearate.

7. A surgical filament of claim 1, coated with from about 0.02 to 0.15 percent of the said mixture.

8. A surgical filament of claim 1, which is comprised of homopolymers or copolymers of lactide or glycolide.

9. A surgical filament of claim 8, wherein said surgical filament is comprised of a copolymer of 10 weight percent lactide and 90 weight percent glycolide.

8

10. A surgical filament of claim 9, which is a braided multifilament suture or ligature.

11. A surgical filament of claim 1, which comprises a homopolymer or a copolymer of p-dioxanone.

12. A surgical filament of claim 1, which is a monofilament suture or ligature.

13. A surgical filament of claim 11, which is a monofilament suture or ligature.

14. A surgical filament of claim 1 which is composed of a polymer selected from the group consisting of the polyolefins and the polyesters.

15. A method for imparting improving and substantially equal dry and wet tiedown properties to a surgical filament which comprises applying to the surface of said surgical filament in the form of a dry powder a water-insoluble, absorbable salt of a C₆ or higher fatty acid, and thereafter removing from the surface of said surgical filament excess said powder by rubbing said surface in intimate contact with a relatively powder free, non-abrasive surface until no powder is visible to the naked eye on said surgical filament surface.

16. The method of claim 15, wherein the fatty acid salt is the salt of calcium, magnesium, barium, aluminum, or zinc.

17. The method of claim 16, wherein said higher fatty acid is selected from the group consisting of C₁₂ to C₂₂ fatty acids and mixtures thereof.

18. The method of claim 15, wherein said surgical filament is an absorbable synthetic polymer selected from the group consisting of homopolymers and copolymers of lactide or glycolide.

19. The method of claim 15, wherein said surgical filament is a nonabsorbable synthetic polymer selected from the group consisting of the polyolefins and the polyesters.

20. The method of claim 16 wherein said surgical filament is a homopolymer or a copolymer of p-dioxanone.

* * * * *

40

45

50

55

60

65

EXHIBIT 31

1 Q. And that's one of the improved handling
2 properties that we were discussing?

3 A. Yes, sir.

4 Q. You said at the end of the sentence, it says
5 "even without a coating"?

6 A. Yes.

7 Q. Does that indicate to you that the composite
8 we're -- the composite we're talking about, I take it, is
9 still the PET/PTFE?

10 A. Correct.

11 Q. That that was uncoated, that composite?

12 A. It certainly sounds that way.

13 Q. Do you know whether there were any tests done
14 with the composite being coated?

15 A. There may very well have. I'm not aware of
16 any.

17 Q. Do you know why it was reported that knot
18 tie-down was better, and they added the words, "even
19 without a coating"?

20 A. Because knot tie-down is an important suture
21 characteristic. With the discovery that the knot
22 tie-down performance was particularly good, I believe
23 that the author wanted to have that recorded.

24 Q. Why did he make the reference, "even without a
25 coating"?

Deposition of:
Dennis D. Jamiolkowski

November 30, 2005

Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. No. 04-12457 PBS

ORIGINAL

DePUY MITEK, INC.,
a Massachusetts corporation,

Plaintiff,

v.

ARTHREX, INC.,
a Delaware corporation,

Defendant.

WEDNESDAY NOVEMBER 30, 2005

Oral deposition of DENNIS D. JAMIOLKOWSKI, taken pursuant to Notice, before Jeanne Cahill, RMR, CRR, at the offices of Woodcock Washburn, LLP, One Liberty Place, 33th Floor, 1650 Market Street, Philadelphia, Pennsylvania, commencing at 9:10 a.m.

1 last sentence in that paragraph that starts "the
2 composite also ranked"?

3 A. Okay. What I would like to do is not miss that
4 second sentence.

5 Q. That's fine.

6 A. I'm going to read the whole thing.
7 "the intrinsic tensile and knot strengths were 87,000
8 pounds per square inch and 48,000 pounds per square inch,
9 respectively. The composite also ranked better" -- oh,
10 "than" -- I can't quite make out that word, but then the
11 following --

12 Q. Is it "silk"?

13 A. Yes, "better than silk and ethabond in knot
14 tie-down, even without a coating." I don't know what the
15 word is between "then" and "silk."

16 Q. What is knot tie-down?

17 A. Beautiful. This description that I had been
18 providing of a surgeon taking the two ends of the suture,
19 putting one inside the other, and now pulling the ends,
20 and sliding that throw down, is knot tie-down. It's
21 the -- it's part of the process of constructing a knot.
22 And again, they will very often have to start these
23 throws well away from the tissue. And knot tie-down -- a
24 good knot tie-down result would be one in which this
25 process is very smooth, with a lack of chatter.

1 A. Because sutures are very frequently coated. In
2 particular, braids are very often coated.

3 **Q. Why is that?**

4 A. Because a braid surface is not very smooth,
5 generally, and consequently, tends to chatter much more
6 than would a monofilament upon knot tie-down. So what
7 the industry has done is that these suture materials that
8 are multifilament in nature, that is, braids, would
9 generally be coated. Not always, but generally.

10 **Q. And why?**

11 A. So as to be able to provide better knot
12 tie-down characteristics. Again, lack of chatter,
13 smoothness during tie-down.

14 **Q. Was it considered an advantage of this suture**
15 **that you could achieve better knot tie-down than ethabond**
16 **and silk even without a coating on the composite?**

17 A. On reading this statement, the author certainly
18 felt that way, it appears.

19 **Q. Does Ethicon feel that way?**

20 A. I would think that it depends on who you talk
21 to at Ethicon, because the advantage of not providing a
22 coating might be economic, but if that is the only
23 characteristic in which it's an advantage, that may not
24 necessarily be the basis of putting a new suture material
25 out.

EXHIBIT 32

Confidential Deposition of:
Neil D. Weber

January 10, 2006

Page 1

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF MASSACHUSETTS
3 C.A. NO. 04-12457 PBS
4

5 DePUY MITEK, INC.,
6 Plaintiffs,

7 vs.

8 ARTHREX, INC., a Delaware
9 corporation,
10 Defendants.
11
12

13 DEPOSITION of DePUY MITEK BY NEIL

14 D. WEBER, called as a witness by and on behalf of
15 the Defendant, pursuant to the applicable
16 provisions of the Federal Rules of Civil Procedure,
17 Rule 30 (b) (6), before P. Jodi Ohnemus, Notary
18 Public, Certified Shorthand Reporter, Certified
19 Realtime Reporter, and Registered Merit Reporter,
20 within and for the Commonwealth of Massachusetts,
21 at the Four Points Sheraton Hotel, 1125 Providence
22 Boston Highway, Norwood, Massachusetts, on Tuesday,
23 10 January, 2006, commencing at 9:08 a.m.
24
25

1 Orthocord's superiority to alternative sutures.

2 Q. Okay. And when you say, "alternative
3 sutures," you're talking about alternative
4 high-strength sutures or alternative sutures
5 generally?

6 A. In general. At this -- I don't know
7 anything more by what's said there.

8 Q. Okay. Does DePuy Mitek promote handling
9 characteristics of Orthocord?

10 A. Yes.

11 Q. Okay. And are these the handling
12 characteristics that are listed there, "Slides,
13 cuts, flexibility," that are promoted by Orthocord
14 -- by DePuy Mitek?

15 A. I'm sure that these are.

16 Q. Among them?

17 A. At least some of them are among them,
18 correct.

19 Q. Right. What is "slides"? What does that
20 refer to?

21 A. I believe it refers to suture sliding
22 through tissue, through instrumentation, and so
23 forth, as well as knots that are tied on the suture
24 sliding down the suture, because, in this case,
25 arthroscopic procedures require a surgeon to tie

1 the knot outside the body and slide the suture into
2 the body.

3 Q. Okay. And is that a handling
4 characteristic of the suture that you just
5 described?

6 A. That's one of many.

7 Q. Okay. What does "cuts" refer to?

8 A. I believe that refers to the ability for a
9 surgeon to cut the suture in a straightforward
10 manner with minimal difficulty.

11 Q. And is that a handle ability
12 characteristic of the suture?

13 A. Yes.

14 Q. Okay. And what does flexibility refer to?

15 A. Flexibility is probably an encompassing
16 term referring to many things. It's clearly -- all
17 these things are very subjective, all these
18 qualities are subjective. This one in particular,
19 probably the first of many different things, but
20 the ability of the suture -- the ability of the
21 surgeon to manipulate the suture in different
22 configurations.

23 Q. What do you mean when you say, "the
24 ability of the surgeon to manipulate the suture in
25 different configurations"?

EXHIBIT 33

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE
CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446
AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

patent is telling a person of ordinary skill in the art that the handleability (*e.g.*, knot tie-down performance) is enhanced due to the braided construction of two dissimilar materials braided together, indeed improved so much in certain configurations that the need for coating can be eliminated.

In addition to pliability and knot tie-down, there are other suture handleability characteristics that were well known in the art at the time of the invention, and therefore, would be understood by a person of ordinary skill in the art to be included in improved handleability, as it is used in the '446 patent. They include tactile feel, compliance, tissue drag, knot security, knot stability, coefficient of friction, stiffness, softness, smoothness, lack of chatter, tissue abrasion and lie-down of the knot. The specification specifically or implicitly mentions some of these (*e.g.*, knot security, knot stability, compliance, stiffness, coefficient of friction, lack of chatter). The others were well known in the suture art at the time of the invention and they were also recognized as such by Ethicon as well. I have reviewed Ethicon documents specifically mentioning these suture handleability characteristics, including documents during the development that lead to the '446 patent. Ex. 7. Mr. Jamiolkowski, one of the original inventors, also confirmed that suture handling properties includes knot tie-down, tactile feel (or hand), pliability, knot security and chatter. Ex. 8 at 140:5-24; 165:16-166:3. Dr. Steckel, another inventor, also confirmed that suture handling is "the ease of manipulation by the surgeon," with handling properties including "pliability, its roughness, smoothness,

EXHIBIT 34



US005147383A

United States Patent [19][11] **Patent Number:** **5,147,383****Bezwada et al.**[45] **Date of Patent:** **Sep. 15, 1992**[54] **SUTURE COATED WITH A POLYVINYL
ESTER**[75] **Inventors:** **Rao S. Bezwada**, Whitehouse Station;
Alastair W. Hunter, Bridgewater,
both of N.J.[73] **Assignee:** **Ethicon, Inc.**, Somerville, N.J.[21] **Appl. No.:** **792,321**[22] **Filed:** **Nov. 12, 1991****Related U.S. Application Data**[62] **Division of Ser. No. 473,505**, Feb. 1, 1990, Pat. No.
5,089,013.[51] **Int. Cl.⁵** **A61L 17/00**[52] **U.S. Cl.** **606/231; 606/228**[58] **Field of Search** **606/228, 231, 230**[56] **References Cited****U.S. PATENT DOCUMENTS**

2,072,303	3/1937	Herrmann et al.	606/231
3,942,532	3/1976	Hunter et al.	606/231
4,027,676	6/1977	Mattei	606/231 X
4,124,748	11/1978	Fujimoto et al.	604/368 X
4,185,637	1/1980	Mattei	606/230
4,201,216	5/1980	Mattei	606/231 X
4,693,939	9/1987	Ofstead	623/5 X
4,844,067	7/1989	Ikada et al.	606/231
4,983,180	1/1991	Kawai et al.	606/231 X

Primary Examiner—Stephen C. Pellegrino*Assistant Examiner*—Jeffrey A. Schmidt*Attorney, Agent, or Firm*—Matthew S. Goodwin[57] **ABSTRACT**

A surgical suture having a coating thereon of at least one polyvinyl ester, and a method for improving the knot tiedown performance of a suture by first coating a polyvinyl ester solution onto the surface of the suture and then removing the solvent from the coated suture.

11 Claims, No Drawings

1

SUTURE COATED WITH A POLYVINYL ESTER

This is a division of application Ser. No. 473,505, filed Feb. 1, 1990, U.S. Pat. No. 5,089,013.

BACKGROUND OF THE INVENTION

This invention relates to coated surgical sutures. More specifically, it relates to sutures coated with a vinyl polymer and to a method for improving the knot tiedown performance of a surgical suture.

Surgical sutures often require a surface coating to improve one or more of their performance properties. For example, a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture, so it passes easily and smoothly through tissue during operative procedures. A monofilament suture may also require a surface coating to reduce the stiff feel of the suture and to increase its pliability.

In response to the need for suitable coatings for surgical sutures, numerous patents have disclosed potential coating compositions. U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,105,034 discloses a multifilament suture coating of a poly(alkylene oxalate), e.g. poly(hexamethylene oxalate). Although the coating compositions disclosed in these patents exhibit excellent handling characteristics and enhance many of the properties of the coated suture, the knot integrity of the coated suture diminishes slightly.

U.S. Pat. No. 3,527,650 discloses a coating of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although PTFE acts as an excellent lubricant to decrease the roughness of multifilament sutures, it has a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application. U.S. Pat. No. 4,043,344 discloses a PLURONICS™ ethylene oxide/propylene oxide copolymer coating for nonabsorbable surgical sutures. Unfortunately, these copolymer coatings lose their lubricity during wet tiedown evaluations.

In view of the deficiencies with the potential candidates for suture coatings, it would be desirable to develop a coating for a suture that can be applied using conventional techniques, that increases the tactile smoothness of the coated suture without sacrificing its physical properties, and that does not adversely affect the knot integrity of the suture.

SUMMARY OF THE INVENTION

In one aspect, the invention is a suture having its surface coated with an amount of at least one polyvinyl ester effective to improve its knot tiedown performance relative to the knot tiedown performance of the uncoated suture.

In another aspect, the invention is a method of improving the knot tiedown performance of a suture. This method comprises the steps of coating the surface of the suture with an effective amount of a solution of at least one polyvinyl ester in an organic solvent, and then removing the solvent from the coated suture.

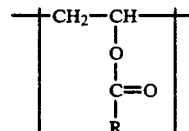
The polyvinyl ester coating of this invention can be applied to the surface of a suture using conventional techniques. The knot tiedown performance of the coated suture, which is an indication of its tactile

2

smoothness, dramatically improves without sacrificing the tensile properties of the coated suture. Surprisingly, these improvements in properties are achieved without adversely affecting the knot security of the coated suture.

DETAILED DESCRIPTION OF THE INVENTION

Polyvinyl (Pv) esters within the scope of this invention are known and can be prepared by conventional techniques, for example, by polymerizing a vinyl ester monomer using a free radical initiation process. Preferably, the PV ester is represented by repeating units of the formula:



wherein R is C₆₋₃₀ straight or branched alkyl.

If the alkyl group of the formula above were to have less than 10 carbons, then the ester would not typically exhibit good coating properties. If the alkyl group were to have greater than 30 carbons, then the availability and purity of the ester would typically not be desirable for coating applications. Preferably, R is C₁₄₋₁₈ straight alkyl. The most preferred PV ester is polyvinyl stearate.

The amount of PV ester coated onto the surface of the suture to improve knot tiedown performance will generally depend on the molecular weight of the PV ester and can readily be determined empirically. In most instances, the required amount of PV ester decreases as its molecular weight increases. Advantageously, the amount of PV ester coated onto the suture ranges from about 0.3 to about 20, preferably from about 0.5 to about 15 percent of the weight of the coated suture. Generally, amounts greater than 20 weight percent may compromise the knot security of the coated suture and amounts below 0.3 weight percent may fail to achieve any significant improvement in suture properties. The suture can be coated with not only one PV ester, but also a mixture of 2 or more PV esters, if desired. Preferably, the suture is coated with one PV ester.

The PV ester coatings of this invention are typically characterized by a weight average molecular weight as determined by gel permeation chromatography ranging from about 50,000 to about 2,000,000, preferably from about 100,000 to about 1,000,000, and most preferably from about 200,000 to about 500,000. A PV ester with molecular weight below 50,000 may fail to significantly improve the knot tiedown of a coated suture, and a PV ester with molecular weight above 2,000,000 may increase the stiffness of the coated suture.

Sutures within the scope of this invention can be of any type used or contemplated for operative procedures. The suture can be synthetic or natural, absorbable or nonabsorbable, or a monofilament or multifilament in a braided, twisted or covered form. In addition, the sutures can be attached to one or more needles, if desired. Examples of absorbable monofilament sutures include natural sutures such as surgical gut and collagen, and synthetic sutures such as homopolymers and copolymers of p-dioxanone. Examples of absorbable multifilament sutures include sutures prepared from polymers of one or more lactones, e.g. VICRYL®

poly(lactide-co-glycolide) multifilament suture. Examples of nonabsorbable monofilament and multifilament sutures include nylon, polypropylene, steel, polyvinylidene fluoride, linen, cotton, silk, and polyesters such as polyethylene terephthalate (PET). The preferred sutures are nonabsorbable, multifilament sutures, preferably polyester sutures. The most preferred suture is PET.

The organic solvent for the PV ester coating of this invention is advantageously a solvent which has a normal boiling point no greater than 120° C. Examples of suitable organic solvents include but are not limited to chlorinated aliphatic solvents such as 1,1,2-trichloroethane and aromatic solvents such as toluene.

The coating can easily be prepared by simply dissolving the PV ester into the appropriate organic solvent. The concentration of the ester in solution will, of course, depend on the amount of PV ester desirably coated onto the surface of the suture, but generally should range from about 3 to about 20, preferably from about 5 to about 15 weight percent.

Once a solution of the PV ester is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc. After the coating is applied, the solvent can be removed by drying in air, or by other techniques well known in the art, for example, removing the solvent at an elevated temperature under vacuum.

The organic solvent and the preparation of a coating solution for application is normally required for coating multifilament sutures. However, an alternative approach is feasible for coating monofilament sutures without requiring the preparation of coating solution. If a synthetic monofilament suture is to be coated, then the fiber-forming polymer from which the suture is derived could be coextruded with a suitably low molecular weight PV ester so that the ester could exude to the surface of the fiber during extrusion to increase its tactile smoothness. Such methods have been demonstrated to enhance the lubricity and knotting characteristics of the fiber-forming polymer.

The PV ester in preferred embodiments of this invention is an essentially nonabsorbable, water insoluble, waxy solid. However, the ester can be modified or additives can be incorporated into the coating composition to tailor coating properties for specific applications. For example, the ester can be made water soluble by copolymerizing the ester with a polyvinyl alcohol and/or polyvinyl pyrrolidone. Alternatively, a vinyl alcohol ester could be copolymerized with vinyl alcohol and/or vinyl pyrrolidone. A bioabsorbable ester especially suited for absorbable sutures can be prepared by first functionalizing a low molecular weight PV ester, and then copolymerizing it with one or more lactones, e.g. glycolide, ε-caprolactone, lactide, p-dioxanone, and the like. Similarly, silicone lubricating agents such as polydimethylsiloxane resins and elastomers, as well as other known polymeric coatings such as homopolymers and copolymers of p-dioxanone and PLURONICS™ ethylene oxide/propylene oxide copolymers, can be added to the coating composition to modify or enhance the final properties of the coated suture. All of these embodiments, as well as similar embodiments to modify or enhance the coated suture properties, are well within the scope of the claimed invention.

Although the PV ester has been described as a coating for surgical sutures, noncoating applications can be readily envisioned. For example, the PV ester may be used as a slip agent in thermo-dye transfer processes, as

an elastomeric component for polyester molding compounds for bumpers and dashboards of automobiles, as a component in tissue adhesives for dentistry and surgery and as a component in jet printing ink applications.

The following example illustrates but is in no way intended to limit the scope of the claimed invention. In the example, the tensile properties, tiedown roughness and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. The straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The tiedown roughness is a measure of the knot tiedown performance. It provides an indication of the force required to slide a knot down a suture, and it is determined generally according to the procedure described in U.S. Pat. No. 3,942,532. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping.

EXAMPLE

For each of three runs, a solution of polyvinyl stearate with a weight average molecular weight of 239,000 and a melting temperature of 48° C. in toluene is prepared. A size 2/0 (USP standard) MERSILENE® PET braided multifilament suture is coated at room temperature with the coating solution using conventional laboratory coating equipment, and the coated suture is subsequently dried in air at 110° F. to remove the toluene. Table 1 compares the tensile and tiedown roughness properties and the knot security characteristics for each of the three runs with an uncoated MERSILENE® PET braided multifilament suture.

TABLE 1

	PROPERTIES OF POLYESTER SUTURE COATED WITH POLYVINYL STEARATE (PVS)			
	PVS COATING CONCENTRATION IN TOLUENE, WT. PERCENT			UNCOATED SUTURE CONTROL
	5.15	8.10	12.15	
Percent Solids ¹ , wt.	0.97	1.74	5.20	—
Suture Diameter, mils.	13.60	13.64	13.93	13.23
Dry Tiedown	140.4	127.8	118.6	355.5
Roughness, gms.				
Wet ² Tiedown	126.2	135.4	137.1	249.2
Roughness, gms.				
Wet Knot Security	4	4	4	4
Dry Knot Tensile Strength, psi	52,567	51,973	50,232	52,458
Wet Knot Tensile Strength, psi	53,971	54,452	48,832	56,794
Dry Straight Tensile Strength, psi	94,882	94,235	91,994	102,946
Percent Elongation	14.70	15.00	16.30	16.27

¹Determined by measuring the difference in weight between the coated and uncoated suture.

²Wet properties are determined after soaking the suture in water at 25° C. for at least 24 hours.

The results indicate that the polyester suture coated with a varying amount of Polyvinyl stearate exhibits significantly improved dry and wet tiedown roughness relative to that of the uncoated suture. The improved roughness is achieved without sacrificing knot security or the tensile properties of the uncoated suture. Gener-

5,147,383

5

ally, a wet tiedown roughness of less than 200 grams, preferably less than 150 grams, for the coated sutures of this invention can be readily obtained.

Similar outstanding results can be obtained with other PV ester coatings within the scope of the claimed invention.

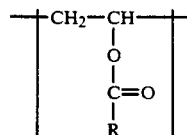
We claim:

1. A suture wherein the outer surface thereof is coated with at least one homopolymer of a vinyl ester monomer in an amount between about 0.3 to about 20 percent of the weight of the coated suture.

2. The suture of claim 1 wherein the surface thereof is coated with one homopolymer of a vinyl ester monomer.

3. The suture of claim 2 wherein the homopolymer is represented by repeating units of the formula:

6



where R is C₆₋₃₀ straight or branched alkyl.

4. The suture of claim 3 wherein R is C₁₄₋₁₈ straight alkyl.

5. The suture of claim 4 wherein the homopolymer is polyvinyl stearate.

6. The suture of claim 5 wherein the molecular weight of the homopolymer is between about 200,00 and about 500,000.

7. The suture of claim 6 wherein the suture is a monofilament or multifilament suture with or without one or more needles.

8. The suture of claim 7 wherein the suture is a multifilament suture.

9. The suture of claim 8 wherein the multifilament suture is a nonabsorbable suture.

10. The suture of claim 9 wherein the suture is a polyester.

11. The suture of claim 10 wherein the polyester is polyethylene terephthalate.

* * * * *

30

35

40

45

50

55

60

65

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 5,147,383
DATED : September 15, 1992
INVENTOR(S) : Rao S. Bezwada and Alastair W. Hunter

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6:

In claim 5 "steasrate" should be -- stearate --.

In claim 6, "issue" should be -- suture --.

In claim 7, "he" should be eliminated.

In claim 8, "he" should be eliminated.

In claim 9, "he" should be -- the --.

In claim 10, "he" should be eliminated.

Signed and Sealed this
Nineteenth Day of October, 1993

Attest:



BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

EXHIBIT 35

United States Patent [19][11] **Patent Number:** **5,089,013****Bezwada et al.**[45] **Date of Patent:** **Feb. 18, 1992**[54] **SUTURE COATED WITH A POLYVINYL ESTER**[75] **Inventors:** **Rao S. Bezwada**, Whitehouse Station;
Alastair W. Hunter, Bridgewater,
both of N.J.[73] **Assignee:** **Ethicon, Inc.**, Somerville, N.J.[21] **Appl. No.:** **473,505**[22] **Filed:** **Feb. 1, 1990**[51] **Int. Cl.⁵** **A61L 17/00**; A01N 1/02;
A61K 1/02[52] **U.S. Cl.** **606/228**; 606/231;
427/2[58] **Field of Search** 606/228, 229, 230, 231;
427/2; 623/5; 604/368[56] **References Cited****U.S. PATENT DOCUMENTS**2,146,295 2/1939 Herrmann et al. 606/229
3,527,650 9/1970 Block .
3,607,848 9/1971 Stoy et al. 623/66 X3,942,532 3/1976 Hunter et al. .
4,027,676 6/1977 Mattei 606/231 X
4,034,344 8/1977 Landi et al. .
4,105,034 8/1978 Shalaby et al. .
4,124,748 11/1978 Fujimoto et al. 604/368 X
4,155,893 5/1979 Fujimoto et al. 604/368 X
4,201,216 5/1980 Mattei 606/230
4,589,873 5/1986 Schwartz et al. 427/2 X
4,693,939 9/1987 Ofstead 623/5 X
4,711,241 12/1987 Lehmann .
4,844,067 7/1989 Ikada et al. 427/2 X*Primary Examiner*—David J. Isabella*Assistant Examiner*—Elizabeth M. Burke*Attorney, Agent, or Firm*—Matthew S. Goodwin[57] **ABSTRACT**

A surgical suture having a coating thereon of at least one polyvinyl ester, and a method for improving the knot tiedown performance of a suture by first coating a polyvinyl ester solution onto the surface of the suture and then removing the solvent from the coated suture.

4 Claims, No Drawings

SUTURE COATED WITH A POLYVINYL ESTER

BACKGROUND OF THE INVENTION

This invention relates to coated surgical sutures. More specifically, it relates to sutures coated with a vinyl polymer and to a method for improving the knot tiedown performance of a surgical suture.

Surgical sutures often require a surface coating to improve one or more of their performance properties. For example, a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture, so it passes easily and smoothly through tissue during operative procedures. A monofilament suture may also require a surface coating to reduce the stiff feel of the suture and to increase its pliability.

In response to the need for suitable coatings for surgical sutures, numerous patents have disclosed potential coating compositions. U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutylate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,105,034 discloses a multifilament suture coating of a poly(alkylene oxalate), e.g. poly(hexamethylene oxalate). Although the coating compositions disclosed in these patents exhibit excellent handling characteristics and enhance many of the properties of the coated suture, the knot integrity of the coated suture diminishes slightly.

U.S. Pat. No. 3,527,650 discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although PTFE acts as an excellent lubricant to decrease the roughness of multifilament sutures, it has a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application. U.S. Pat. No. 4,043,344 discloses a PLURONICS ethylene oxide/propylene oxide copolymer coating for nonabsorbable surgical sutures. Unfortunately, these copolymer coatings lose their lubricity during wet tiedown evaluations.

In view of the deficiencies with the potential candidates for suture coatings, it would be desirable to develop a coating for a suture that can be applied using conventional techniques, that increases the tactile smoothness of the coated suture without sacrificing its physical properties, and that does not adversely affect the knot integrity of the suture.

SUMMARY OF THE INVENTION

In one aspect, the invention is a suture having its surface coated with an amount of at least one polyvinyl ester effective to improve its knot tiedown performance relative to the knot tiedown performance of the uncoated suture.

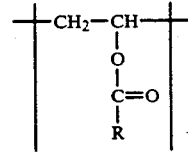
In another aspect, the invention is a method of improving the knot tiedown performance of a suture. This method comprises the steps of coating the surface of the suture with an effective amount of a solution of at least one polyvinyl ester in an organic solvent, and then removing the solvent from the coated suture.

The polyvinyl ester coating of this invention can be applied to the surface of a suture using conventional techniques. The knot tiedown performance of the coated suture, which is an indication of its tactile smoothness, dramatically improves without sacrificing the tensile properties of the coated suture. Surprisingly, these improvements in properties are achieved without

adversely affecting the knot security of the coated suture.

DETAILED DESCRIPTION OF THE INVENTION

Polyvinyl (PV) esters within the scope of this invention are known and can be prepared by conventional techniques, for example, by polymerizing a vinyl ester monomer using a free radical initiation process. Preferably, the PV ester is represented by repeating units of the formula:



wherein R is C₆₋₃₀ straight or branched alkyl.

If the alkyl group of the formula above were to have less than 10 carbons, then the ester would not typically exhibit good coating properties. If the alkyl group were to have greater than 30 carbons, then the availability and purity of the ester would typically not be desirable for coating applications. Preferably, R is C₁₄₋₁₈ straight alkyl. The most preferred PV ester is polyvinyl stearate.

The amount of PV ester coated onto the surface of the suture to improve knot tiedown performance will generally depend on the molecular weight of the PV ester and can readily be determined empirically. In most instances, the required amount of PV ester decreases as its molecular weight increases. Advantageously, the amount of PV ester coated onto the suture ranges from about 0.3 to about 20, preferably from about 0.5 to about 15 percent of the weight of the coated suture. Generally, amounts greater than 20 weight percent may compromise the knot security of the coated suture and amounts below 0.3 weight percent may fail to achieve any significant improvement in suture properties. The suture can be coated with not only one PV ester, but also a mixture of 2 or more PV esters, if desired. Preferably, the suture is coated with one PV ester.

The PV ester coatings of this invention are typically characterized by a weight average molecular weight as determined by gel permeation chromatography ranging from about 50,000 to about 2,000,000, preferably from about 100,000 to about 1,000,000, and most preferably from about 200,000 to about 500,000. A PV ester with molecular weight below 50,000 may fail to significantly improve the knot tiedown of a coated suture, and a PV ester with molecular weight above 2,000,000 may increase the stiffness of the coated suture.

Sutures within the scope of this invention can be of any type used or contemplated for operative procedures. The suture can be synthetic or natural, absorbable or nonabsorbable, or a monofilament or multifilament in a braided, twisted or covered form. In addition, the sutures can be attached to one or more needles, if desired. Examples of absorbable monofilament sutures include natural sutures such as surgical gut and collagen, and synthetic sutures such as homopolymers and copolymers of p-dioxanone. Examples of absorbable multifilament sutures include sutures prepared from fiber-forming polymers of one or more lactones, e.g. VICRYL® poly(lactide-co-glycolide) multifilament

3

suture. Examples of nonabsorbable monofilament and multifilament sutures include nylon, polypropylene, steel, polyvinylidene fluoride, linen, cotton, silk, and polyesters such as polyethylene terephthalate (PET). The preferred sutures are nonabsorbable, multifilament sutures, preferably polyester sutures. The most preferred suture is PET.

The organic solvent for the PV ester coating of this invention is advantageously a solvent which has a normal boiling point no greater than 120° C. Examples of suitable organic solvents include but are not limited to chlorinated aliphatic solvents such as 1,1,2-trichloroethane and aromatic solvents such as toluene.

The coating can easily be prepared by simply dissolving the PV ester into the appropriate organic solvent. The concentration of the ester in solution will, of course, depend on the amount of PV ester desirably coated onto the surface of the suture, but generally should range from about 3 to about 20, preferably from about 5 to about 15 weight percent.

Once a solution of the PV ester is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc. After the coating is applied, the solvent can be removed by drying in air, or by other techniques well known in the art, for example, removing the solvent at an elevated temperature under vacuum.

The organic solvent and the preparation of a coating solution for application is normally required for coating multifilament sutures. However, an alternative approach is feasible for coating monofilament sutures without requiring the preparation of coating solution. If a synthetic monofilament suture is to be coated, then the fiber-forming polymer from which the suture is derived could be coextruded with a suitably low molecular weight PV ester so that the ester could exude to the surface of the fiber during extrusion to increase its tactile smoothness. Such methods have been demonstrated to enhance the lubricity and knotting characteristics of the fiber-forming polymer.

The PV ester in preferred embodiments of this invention is an essentially nonabsorbable, water insoluble, waxy solid. However, the ester can be modified or additives can be incorporated into the coating composition to tailor coating properties for specific applications. For example, the ester can be made water soluble by copolymerizing the ester with a polyvinyl alcohol and/or polyvinyl pyrrolidone. Alternatively, a vinyl alcohol ester could be copolymerized with vinyl alcohol and/or vinyl pyrrolidone. A bioabsorbable ester especially suited for absorbable sutures can be prepared by first functionalizing a low molecular weight PV ester, and then copolymerizing it with one or more lactones, e.g. glycolide, ϵ -Caprolactone, lactide, p-dioxanone, and the like. Similarly, silicone lubricating agents such as polydimethylsiloxane resins and elastomers, as well as other known polymeric coatings such as homopolymers and copolymers of p-dioxanone and PLURON-ICS ethylene oxide/propylene oxide copolymers, can be added to the coating composition to modify or enhance the final properties of the coated suture. All of these embodiments, as well as similar embodiments to modify or enhance the coated suture properties, are well within the scope of the claimed invention.

Although the PV ester has been described as a coating for surgical sutures, noncoating applications can be readily envisioned. For example, the PV ester may be used as a slip agent in thermo-dye transfer processes, as

4

an elastomeric component for polyester molding compounds for bumpers and dashboards of automobiles, as a component in tissue adhesives for dentistry and surgery and as a component in jet printing ink applications.

The following example illustrates but is in no way intended to limit the scope of the claimed invention. In the example, the tensile properties, tiedown roughness and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The tiedown roughness is a measure of the knot tiedown performance. It provides an indication of the force required to slide a knot down a suture, and it is determined generally according to the procedure described in U.S. Pat. No. 3,942,532. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tying a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tying knots with additional throws until 20 out of 20 knots break cleanly without slipping.

EXAMPLE

For each of three runs, a solution of polyvinyl stearate with a weight average molecular weight of 239,000 and a melting temperature of 48° C. in toluene is prepared. A size 2/0 (USP standard) MERSILENE® PET braided multifilament suture is coated at room temperature with the coating solution using conventional laboratory coating equipment, and the coated suture is subsequently dried in air at 110° F. to remove the toluene. Table 1 compares the tensile and tiedown roughness properties and the knot security characteristics for each of the three runs with an uncoated MERSILENE PET braided multifilament suture.

TABLE 1

	PVS COATING CONCENTRATION IN TOLUENE, WT. PERCENT			UNCOATED SUTURE CONTROL
	5.15	8.10	12.15	
Percent Solids ¹ , wt.	0.97	1.74	5.20	—
Suture Diameter, mils.	13.60	13.64	13.93	13.23
Dry Tiedown	140.4	127.8	118.6	355.5
Roughness, gms.				
Wet Tiedown	126.2	135.4	137.1	249.2
Roughness, gms.				
Wet Knot Security	4	4	4	4
Dry Knot Tensile	52,567	51,973	50,232	52,458
Strength, psi				
Wet Knot Tensile	53,971	54,452	48,832	56,794
Strength, psi				
Dry Straight	94,882	94,235	91,994	102,946
Tensile Strength, psi				
Percent Elongation	14.70	15.00	16.30	16.27

¹Determined by measuring the difference in weight between the coated and uncoated suture.

²Wet properties are determined after soaking the suture in water at 25° C. for at least 24 hours.

The results indicate that the polyester suture coated with a varying amount of polyvinyl stearate exhibits significantly improved dry and wet tiedown roughness relative to that of the uncoated suture. The improved roughness is achieved without sacrificing knot security or the tensile properties of the uncoated suture. Gener-

5

ally, a wet tiedown roughness of less than 200 grams, preferably less than 150 grams, for the coated sutures of this invention can be readily obtained.

Similar outstanding results can be obtained with other PV ester coatings within the scope of the claimed invention.

We claim:

1. A method of improving the knot tiedown performance of a suture comprising the steps of:

a) coating an outer surface of the suture with a solution of at least one homopolymer of a vinyl ester monomer in an organic solvent, and then

6

b) removing the solvent from the coated suture so as to coat the suture with an amount of the homopolymer from 0.3 to 20 percent of the weight of the coated suture.

2. The method of claim 1 wherein the solution of the homopolymer of a vinyl ester monomer is a solution of between 0.5 to 15 weight percent of the homopolymer in toluene.

3. The method of claim 2 wherein the solvent is removed by drying the coated surface in air.

4. The method of claim 3 wherein the coated suture is dried at a temperature greater than room temperature.

* * * * *

15

20

25

30

35

40

45

50

55

60

65

EXHIBIT 36

United States Patent [19]**Bezwada et al.**[11] **Patent Number:** **4,994,074**[45] **Date of Patent:** **Feb. 19, 1991**

[54] **COPOLYMERS OF
EPSILON-CAPROLACTONE, GLYCOLIDE
AND GLYCOLIC ACID FOR SUTURE
COATINGS**

[75] **Inventors:** **Rao S. Bezwada**, Whitehouse Station;
Alastair W. Hunter, Bridgewater;
Shalaby W. Shalaby, Lebanon, all of
N.J.

[73] **Assignee:** **Ethicon, Inc.**, Somerville, N.J.

[21] **Appl. No.:** **473,291**

[22] **Filed:** **Feb. 1, 1990**

[51] **Int. Cl.⁵** **C08G 63/06; C08G 63/08**

[52] **U.S. Cl.** **606/230; 528/354**

[58] **Field of Search** 528/354; 606/230, 228,
606/231

[56] **References Cited****U.S. PATENT DOCUMENTS**

4,045,418 8/1977 Sinclair 528/354 X
4,057,537 11/1977 Sinclair 528/354 X
4,243,775 1/1981 Rosensaft et al. 528/354 X
4,300,565 11/1981 Rosensaft et al. 529/354 X
4,595,713 6/1986 St. John 528/354 X
4,605,730 8/1986 Shalaby et al. .
4,624,256 11/1986 Messier et al. .
4,700,704 10/1987 Jamiolkowski et al. .
4,788,979 12/1988 Jarret et al. .
4,791,929 12/1980 Jarret et al. .

Primary Examiner—Earl Nielsen

Attorney, Agent, or Firm—Matthew S. Goodwin

[57] **ABSTRACT**

Copolymer of a predominant amount of ϵ -caprolactone, the balance being glycolide and glycolic acid. Coating for an absorbable, multifilament surgical suture prepared by dissolving the copolymer in an organic solvent.

16 Claims, No Drawings

4,994,074

1

COPOLYMERS OF EPSILON-CAPROLACTONE, GLYCOLIDE AND GLYCOLIC ACID FOR SUTURE COATINGS

BACKGROUND OF THE INVENTION

This invention relates to copolymers of ϵ -caprolactone and glycolide, and more specifically, to such copolymers with improved properties especially adapted for use as coatings for absorbable multifilament surgical sutures.

Multifilament surgical sutures such as Vicryl® poly(lactide-co-glycolide) multifilament suture typically require a surface coating to improve the pliability and knotting characteristics of the suture. A polymer coating which has recently been developed and shows significant promise as a suture coating is derived from a polymer solution of ϵ -caprolactone in an appropriate organic solvent. The coating solution is typically applied to the surface of the suture using conventional techniques, and then the solvent is removed. Polycaprolactone is a biocompatible polymer with a relatively low melting point, a property which is essential for good coating characteristics. Additionally, sutures coated with polycaprolactone exhibit enhanced pliability and handling characteristics. Unfortunately, polycaprolactone homopolymer is essentially nonabsorbable because it retains some of its mass and mechanical integrity in vivo for periods up to one year, which is too long for numerous surgical applications.

In an effort to improve the bioabsorbability and other properties of a polycaprolactone coating polymer, the polymer composition has been modified by incorporating copolymerizable monomers or lubricating agents therein. For example, U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ -caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare polymer fibers or coatings for multifilament sutures. U.S. Pat. No. 4,791,929 discloses a bioabsorbable coating of a copolymer of at least 50 percent ϵ -caprolactone and glycolide. Sutures coated with such copolymers are reported to be less stiff than sutures coated with other materials, and the physical properties of the coated suture are also reported to be acceptable.

Unfortunately, the problem of adequate bioabsorbability of homopolymers and copolymers of ϵ -caprolactone for suture coating applications still remains. One of the difficulties a skilled polymer chemist has faced in solving this problem is in developing a faster absorbing polymer of ϵ -caprolactone without sacrificing the physical properties of multifilament sutures coated with such a polymer. In view of the deficiencies with the known art polycaprolactone coatings, it would be most desirable to accomplish this goal.

SUMMARY OF THE INVENTION

In one aspect, the invention is a copolymer of a predominant amount of ϵ -caprolactone, and the balance glycolide and glycolic acid. The copolymer is characterized by a concentration of glycolic acid such that the intrinsic viscosity of the copolymer in hexafluoroisopropyl alcohol (HFIP) is between about 0.15 to about 0.60 deciliters per gram (dl/g).

2

In another aspect, the invention is a coating for a surgical suture. This coating comprises a solution of the copolymer described above in an organic solvent.

Surprisingly, the use of glycolic acid as a comonomer into the copolymers of this invention increases the rate of absorption of the copolymers relative to the absorption rate of prior art copolymers of ϵ -caprolactone and glycolide. This increase in the rate of absorption is achieved while maintaining the physical properties of sutures coated with such copolymers, for example, tissue drag, which measures the degree of trauma associated with passing the coated suture through tissue, knot tiedown characteristics and tensile properties.

The copolymers of this invention and the coatings derived therefrom can be used for coating bioabsorbable, multifilament surgical sutures.

DETAILED DESCRIPTION OF THE INVENTION

A predominant amount of ϵ -caprolactone generally refers to an amount of ϵ -caprolactone greater than 50 mole percent of the comonomer composition from which the copolymer of this invention is derived. ϵ -Caprolactone is the predominant component of the copolymer because of its low melting temperature and its ability to enhance the physical properties of coated multifilament sutures. Preferably, the amount of ϵ -caprolactone used ranges from about 80 to about 95, more preferably from about 90 to about 95 mole percent.

The remaining comonomers of the copolymer of this invention are glycolide and glycolic acid. The amount of glycolic acid in the comonomer composition from which the copolymer is derived is an amount such that the intrinsic viscosity of the copolymer in a 0.1 g/dl solution of HFIP at 25° C. is between about 0.15 to about 0.60 dl/g. Preferably, the intrinsic viscosity of the copolymer is between about 0.20 to about 0.50 dl/g. The glycolic acid can be used in part to control the molecular weight of the copolymer, and therefore its intrinsic viscosity, and, in combination with the glycolide comonomer, can be used to lower the melting temperature of the copolymer relative to that of a polycaprolactone homopolymer. Advantageously, the crystalline melting temperature of the copolymer is between about 30° to about 60° C., preferably between about 35° to about 50° C. The frequency of the hydrolytically labile linkages associated with the use of glycolic acid along the chains of the copolymer is also responsible for enhancing the absorption profile of the coating.

The adjustment of the intrinsic viscosity of the copolymer by varying the concentration of glycolic acid is important to achieve a copolymer coating that will not only form a film on the outer surface of the suture but also penetrate and distribute evenly into the interstices of the multifilament fibers. This penetration and the subsequent adsorption of the coating polymer onto individual fibers of the multifilament increases the pliability of the suture and enhances its knotting characteristics, specifically the ease with which a knot can slide down the length of the suture during an operative procedure. Likewise, the control of the crystalline melting temperature, which to a significant degree is controlled by the intrinsic viscosity, by varying the relative proportions of glycolide and glycolic acid is important to achieve similar improvements in the properties of coated sutures.

4,994,074

3

Advantageously, the amount of glycolic acid in the comonomer composition from which the copolymer is derived to achieve an acceptable intrinsic viscosity and to increase the rate of absorption relative to the prior art copolymers of ϵ -caprolactone and glycolide ranges from about 1 to about 15, preferably from about 2 to about 10 mole percent. The glycolide comonomer not only lowers the melting temperature of the copolymer, but also, to a lesser extent relative to glycolic acid, increases the rate of absorption and is preferably present in the comonomer composition at a concentration ranging from about 5 to about 20, more preferably from about 5 to about 10 mole percent. The mole ratio of glycolide to glycolic acid to achieve desired coating properties advantageously ranges from about 20:80 to about 95:5, preferably from about 70:30 to about 90:10.

The copolymers of this invention can be prepared by polymerizing in the presence of an organometallic catalyst the desired amounts of ϵ -caprolactone, glycolide and glycolic acid at an elevated temperature, e.g. 160° to 190° C., for a time sufficient to achieve the desired intrinsic viscosity. The organometallic catalyst is preferably a tin-based catalyst, preferably stannous octoate, and is present in the reaction mixture at a mole ratio of monomer to catalyst between 10,000 to 90,000 to 1, preferably 15,000 to 30,000 to 1.

The organic solvent for the polymer coating of this invention is advantageously a solvent which has a normal boiling point no greater than 120° C. Examples of suitable organic solvents include but are not limited to chlorinated aliphatic solvents such as 1,1,2-trichloroethane, aromatic solvents such as toluene, and aliphatic ketones such as acetone.

The coating can easily be prepared by simply dissolving the copolymer of this invention into the appropriate organic solvent. The concentration of the copolymer in solution desirably ranges from about 1 to about 20, preferably from about 10 to about 15 weight percent. Generally, concentrations greater than 20 weight percent polymer provide coating solutions which are too viscous to achieve adequate penetration of the coating solution into the interstices of the fibers, and concentrations below 1 weight percent are inadequate to properly coat a sufficient amount of copolymer onto the suture, although it may be possible but inconvenient to employ two or more coating steps to achieve a sufficient coating concentration on the copolymer. Once a solution of the copolymer is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc. After the coating is applied, the solvent can be removed by drying in air, or by other techniques well known in the art, for example, removing the solvent at an elevated temperature under vacuum.

The suture to be coated can be a monofilament or multifilament suture. Preferably, a multifilament suture

4

in a braided, twisted, crocheted, knitted or covered form is used. Preferably, the suture is an absorbable, multifilament braided suture. The preferred absorbable sutures are those prepared from a polymer of a lactone or a polymer of one or more lactones. Examples of the most widely used lactones for suture preparation are lactide, glycolide and ϵ -caprolactone. The most preferred suture is Vicryl® poly(lactide-co-glycolide) multifilament braided suture. For numerous surgical applications, the suture is attached to one or more needles.

The following examples illustrate the claimed invention and are in no way intended to limit its scope.

EXAMPLE 1

COPOLYMER OF ϵ -CAPROLACTONE/GLYCOLIDE/GLYCOLIC ACID AT 0.90/0.05/0.10 MOLE RATIO

A flame dried, 250 ml, round bottom single neck flask is charged with 102.73 g (0.9 mole) of ϵ -caprolactone, 5.80 g (0.05 mole) of glycolide, 7.61 g (0.10 mole) of glycolic acid, and 0.121 milliliters of stannous octoate (0.33 molar in toluene). The flask is fitted with a flame dried mechanical stirrer. The reactor is purged with nitrogen three times before venting with nitrogen. The reaction mixture is heated to 160° C. and maintained at this temperature for 24 hours. The copolymer is isolated, characterized, and tested for absorption. The results are reported in Table 1.

EXAMPLE 2

COPOLYMER OF ϵ -CAPROLACTONE/GLYCOLIDE/GLYCOLIC ACID AT 0.90/0.08/0.04 BY MOLE

The procedure of Example 1 is repeated, except that the reaction flask is charged with 9.29 g (0.08 mole) of glycolide and 3.04 g (0.04 mole) of glycolic acid.

COMPARATIVE EXAMPLE 1

COPOLYMER OF ϵ -CAPROLACTONE/GLYCOLIDE AT 90/10 BY WT. (90/10 BY MOLE)

A flame dried, 250 ml, round bottom, single neck flask is charged with 90 g (0.789 mole) of ϵ -caprolactone, 10 g (0.0862 mole) of glycolide, 7.96 ml (40 millimole/mole of total monomer) of distilled 1-dodecanol, and 0.121 ml of stannous octoate (0.33 molar solution in toluene). The reaction flask is purged with nitrogen three times before venting with nitrogen. The reaction mixture is heated to 180° C. and maintained there for 4.5 hours. The copolymer is isolated, characterized, and tested for absorption. The results are reported in Table 1.

TABLE 1

CHARACTERIZATION AND ABSORPTION OF COATING COPOLYMERS			
Example No.	1	2	Comparative Example 1
<u>Characterization</u>			
Copolymer comp.	90/5/10 by mole	90/8/4 by mole	90/10/0 by wt. (90/10/0 by mole)
caprolactone/glycolide/GA ¹			
Intrinsic Viscosity of	0.19	0.31	0.28
copolymer in HFIP, dl/g			
Melting Point ²	41-44° C.	42-40° C.	35-45° C.
<u>Absorption</u>			
In Vitro hydrolysis at 100° C.			
(sterile water)			
Percent nonhydrolyzed			

4,994,074

5

6

TABLE 1-continued

CHARACTERIZATION AND ABSORPTION OF COATING COPOLYMERS			
Example No.	1	2	Comparative Example 1
copolymer ³ at			
2 days	19.79	25.76	77.23
2 days (repeat)	15.82	35.23	81.80

¹Glycolic acid²Determined by hot stage microscopy³Determined by measuring weight loss of copolymer after the indicated number of days

The data from Table 1 shows a significant increase in the rate of hydrolysis for the copolymers of this invention compared to prior art copolymers of ϵ -caprolactone and glycolide. The rate of hydrolysis is a measure of the rate of absorption since synthetic copolymers 15 degrade via hydrolysis.

A 10 and 15 percent coating solution of each of the copolymers of Examples 1 and 2, and Comparative Example 1, in toluene is prepared. A size 2/0 (USP standard) Vicryl® poly(lactide-co-glycolide) braided 20 multifilament suture is coated with each coating solution using conventional laboratory coating equipment. The physical properties of the coated sutures are evaluated and the results are reported in Table 2 as Examples 3, 4, and Comparative Example 2, which correspond to 25 Examples 1, 2, and Comparative Example 1, respectively.

3. The copolymer of claim 2 wherein the amount of ϵ -caprolactone is between about 90 to about 95 mole percent.

4. The copolymer of claim 3 wherein the intrinsic viscosity of the copolymer is between about 0.20 to about 0.50 dl/g.

5. The copolymer of claim 4 wherein the melting temperature of the copolymer is between about 35° to about 50° C.

6. The copolymer of claim 5 wherein the amount of glycolic acid is between about 1 to about 15 mole percent.

7. The copolymer of claim 6 wherein the amount of glycolide is between about 2 to about 10 mole percent.

8. A coating for a surgical suture comprising a solution of the copolymer of claim 1 or 7 in an organic solvent.

TABLE 2

PHYSICAL PROPERTIES OF SUTURES COATED WITH COPOLYMERS						
	Example No.					
	3		4		Comparative Example 2	
	10% Sol.	15% Sol.	10% Sol.	15% Sol.	10% Sol.	15% Sol.
	caprolactone/ glycolide/GA ¹ Copolymer 90/5/10 by mole IV = 0.19 dl/g		caprolactone/ glycolide/GA ¹ copolymer 90/8/4 by mole IV = 0.31 dl/g		caprolactone/ glycolide/GA ¹ copolymer 90/10/0 by wt. (90/10/0 by mole) IV = 0.28 dl/g	
Dia., (mils)	12.6	12.7	12.8	12.7	12.9	12.9
Tissue Drag ² , gms	18.34	22.13	22.13	17.00	32.25	14.54
Wet Roughness Tiedown ³ , gms	310.32	353.98	137.89	113.41	149.66	124.40
Percent Elong. ⁴	17.7	18	16.6	17.3	17.6	17.3
Dry Knot Tensile ⁴ , psi	73,800	72,600	73,800	69,500	71,900	68,800
Wet Knot Tensile ⁴ , psi	75,400	71,800	73,000	71,000	71,900	70,400
Dry Str. Tensile ⁴ , psi	124,300	121,600	116,600	119,200	112,500	113,200

¹Glycolic acid²Tissue Drag is a measure of the relative smoothness of the suture while passing through tissue, and is determined by using an Instron Tensile Tester and a recording device.³Tiedown measured on a Table-Model Instron Tensile Tester as described in U.S. Pat. No. 3,942,532.⁴Tensile properties and elongation determined generally according to the procedures outlined in U.S. Pat. No. 4,838,267. Wet tensile properties were measured after immersing the coated suture in water at 25° C. for 24 hours.

The data from Table 2 illustrates comparable physical properties achieved for sutures coated with the copolymers of this invention relative to the physical properties of sutures coated with prior art copolymers of ϵ -caprolactone and glycolide.

Similar outstanding results can be obtained by varying the mole ratio of each of the comonomer components of the copolymer. A coated suture with tailor-made properties can be prepared by selecting an appropriate multifilament suture with the desired coating copolymer.

We claim:

1. A copolymer of a predominant amount of ϵ -caprolactone and the balance glycolide and glycolic acid, at a concentration of glycolic acid such that the intrinsic viscosity of the copolymer in hexafluoroisopropyl alcohol is between about 0.15 to about 0.60 dl/g.

2. The copolymer of claim 1 wherein the amount of ϵ -caprolactone is between about 80 to about 95 mole percent.

9. The coating of claim 8 wherein the amount of copolymer in solution is between about 1 to about 20 weight percent.

10. The coating of claim 9 wherein the suture is an absorbable monofilament or multifilament suture with or without an attached needle.

11. The coating of claim 10 wherein the suture is an absorbable multifilament suture.

12. The coating of claim 11 wherein the absorbable multifilament suture is in the form of a braid.

13. The coating of claim 12 wherein the suture is prepared from a polymer of a lactone or one or more lactones.

14. The coating of claim 13 wherein the multifilament suture is a poly(lactide-co-glycolide) braided multifilament suture.

15. An absorbable multifilament suture coated with the copolymer of claim 1.

16. An absorbable multifilament suture coated with the copolymer of claim 7.

* * * * *

EXHIBIT 37



US005312437A

United States Patent [19][11] **Patent Number:** **5,312,437****Hermes et al.**[45] **Date of Patent:** **May 17, 1994**[54] **ABSORBABLE COATING COMPOSITION
AND SUTURE COATED THEREWITH**[75] **Inventors:** **Matthew E. Hermes, Easton; Donald
S. Kaplan, Weston; Nagabhushanam
Totakura, Norwalk; Steven L.
Bennett, Milford, all of Conn.**[73] **Assignee:** **United States Surgical Corporation,
Norwalk, Conn.**[21] **Appl. No.:** **896,856**[22] **Filed:** **Jun. 12, 1992**[51] **Int. Cl.⁵** **A61L 17/00**[52] **U.S. Cl.** **606/230; 606/231;
428/375; 428/378**[58] **Field of Search** **606/230, 231; 428/275,
428/375, 378; 525/354, 408**[56] **References Cited****U.S. PATENT DOCUMENTS**

3,531,561	9/1970	Trehu	606/231
3,867,190	2/1975	Schmitt et al.	606/231
3,942,532	3/1976	Hunter et al.	606/230
4,027,676	6/1977	Mattei	606/230
4,043,344	8/1977	Landi et al.	606/230
4,047,533	9/1977	Perciaccante	606/230
4,080,969	3/1978	Casey et al.	606/231
4,105,034	8/1978	Shalaby et al.	606/230

4,185,637	1/1980	Mattei	606/230
4,201,216	5/1980	Mattei	606/230
4,470,416	9/1984	Kafrawy et al.	606/230
4,624,256	11/1986	Messier et al.	606/230
4,649,920	3/1987	Rhum	606/237
4,653,497	3/1987	Bezwada et al.	606/230
4,705,820	11/1987	Wang et al.	606/230
4,711,241	12/1987	Lehmann	606/230
4,716,203	12/1987	Casey et al.	606/230
4,744,365	5/1988	Kaplan et al.	606/230
4,788,979	12/1988	Jarrett et al.	606/230
4,857,602	8/1989	Casey et al.	606/230
5,123,912	6/1992	Kaplan et al.	606/230

FOREIGN PATENT DOCUMENTS

0239775 10/1987 European Pat. Off. 606/77

Primary Examiner—Stephen C. Pellegrino*Assistant Examiner*—Gary Jackson[57] **ABSTRACT**

An absorbable composition for application to a surgical suture to improve the knot tie-down and/or knot security characteristics thereof is obtained from the reaction of a poly(oxypopylene) glycol and a lactide/glycolide copolymer, optionally, in the presence of an initiator and/or catalyst.

36 Claims, No Drawings

1

5,312,437

2

ABSORBABLE COATING COMPOSITION AND SUTURE COATED THEREWITH

BACKGROUND OF THE INVENTION

This invention relates to an absorbable coating composition for surgical sutures and to a coated surgical suture exhibiting improved knot tie-down and/or knot security characteristics.

Since monofilament synthetic absorbable suture materials are generally stiffer than their catgut or collagen counterparts, multifilament, e.g., braided or twisted, constructions have been employed in many instances for greater softness and flexibility. Multifilament sutures, however, exhibit a certain degree of undesirable roughness in what is generally referred to as knot tie-down performance, i.e., the ease or difficulty of sliding a knot into place down the suture. It has therefore become a common practice to coat sutures, particularly those of the multifilament variety, with compositions which improve their knot tie-down performance and perhaps one or more other properties of the sutures as well. Known suture coating compositions include those described in U.S. Pat. Nos. 3,867,190; 3,942,532; 4,027,676; 4,043,344; 4,047,533; 4,080,969; 4,105,034; 4,185,637; 4,201,216; 4,470,416; 4,624,256; 4,649,020; 4,716,203; 4,788,979; and, 4,857,602.

U.S. patent application Ser. No. 07/707,437, filed May 28, 1991 describes an absorbable composition for improving the knot tie-down properties of a suture, the composition being either a copolymer derived from the copolymerization of a low molecular weight poly(oxyethylene) glycol, glycolide monomer and a lactide monomer or a copolymer derived from the copolymerization of a low molecular weight polyalkylene glycol and a preformed copolymer of lactide and glycolide.

Notwithstanding the extensive research in attempting to improve the tie-down characteristics of surgical sutures, sutures having even further improved knot tie-down properties are still desirable.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an absorbable coating composition for surgical sutures, particularly multifilament synthetic sutures.

Another object of this invention is to provide a coated surgical suture exhibiting improved knot tie-down characteristics.

Still another object of the present invention is to provide an absorbable coated synthetic suture exhibiting improved knot tie-down characteristics under both wet and dry conditions.

A further object of this invention is to provide an absorbable coated synthetic suture exhibiting improved knot security characteristics.

These and other objects are achieved herein by providing an absorbable coating composition comprising the product obtained by reacting a mixture of poly(oxypropylene) glycol and a lactide/glycolide copolymer in the presence or absence of an initiator. Coated sutures having improved knot tie-down characteristics under dry and wet conditions as well as improved knot security characteristics are provided by depositing a coating of the afore-described composition on the suture.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The preferred poly(oxypropylene) glycols used in preparing the suture coating composition of this invention possess molecular weights ranging from about 400 to about 6,000 and more preferably from about 1,000 to about 4,000 and viscosities of from about 70 to about 2,000 cp, preferably from about 150 to about 1,200 cp and, more preferably, from about 900 to about 1200 cp. Suitable poly(oxypropylene) glycols include those of the Pluracol (BASF-Wyandotte), Voranol (Dow), Poly G (Olin), Polylyte (Reichhold), Thanol (Texaco) and Niaux (Union Carbide) series.

The preferred lactide/glycolide copolymers are made from about 90 to about 65 mole percent lactide, from about 10 to about 35 mole percent glycolide and from 0 to about 5 mole percent of one or more additional monomers copolymerizable therewith such as p-dioxanone, ϵ -caprolactone, etc. Copolymers of this type and their preparation are known, e.g., from U.S. Pat. Nos. 2,668,162; 2,703,316; 3,297,033; 3,620,218; 3,636,956; 3,736,646; 3,773,919; 3,797,499; 3,839,297; 3,867,190; 3,982,543; 4,273,920; and, 4,523,591.

More preferred lactide/glycolide copolymers for use in preparing the coating composition herein are the 85-70 mole percent lactide/15-30 mole percent glycolide copolymers described in U.S. Pat. No. 4,523,591, the contents of which are incorporated by reference herein. The copolymers are advantageously prepared with L-lactide and possess a glass transition temperature of at least about 54° C. when measured by differential scanning calorimetry at 20° C./min and an inherent viscosity of at least about 0.9 when measured in chloroform at a concentration of 0.25 g/dl. A particularly preferred lactide/glycolide copolymer is prepared with about 18 mole percent lactide and about 82 mole percent glycolide.

The absorbable coating composition herein is prepared by reacting the poly(oxypropylene) glycol(s) with the lactide/glycolide copolymer(s), generally in the presence of an esterification catalyst such as stannous chloride, stannous octoate, etc., and, optionally, an initiator. Suitable initiators include glycols such as ethylene glycol, propylene glycol, diethylene glycol and dipropylene glycol. A preferred glycol, diethylene glycol, is advantageously employed at a level of from about 0.01 to about 0.1 weight percent, and preferably at a level of from about 0.02 to about 0.5 weight percent, of the reaction medium. The weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer can vary from about 4:1 to about 1:4 and preferably from about 2:1 to about 1:2, respectively. Typically, the reaction is carried out in an inert atmosphere, e.g., nitrogen, at temperatures, for example, of from about 125° to about 200° C., and preferably from about 150° to about 160° C. When employing a lactide/glycolide copolymer possessing an inherent viscosity of at least about 0.9, it is preferred to carry out the reaction until the inherent viscosity of the coating composition has fallen below about 0.9, and more preferably below about 0.5, when measured in chloroform at a concentration of 0.25 g/dl. Reaction periods of from about 10 to about 24 hours are generally sufficient to accomplish this.

The absorbable coating composition of the present invention is non-toxic and physiologically inert. It can be applied to the surface of a suture in the form of a solution and/or dispersion in a volatile carrier such as

5,312,437

3

methylen chloride or acetone. Solidification of the coating on the suture surface occurs upon evaporation of the carrier.

The coating composition can be applied to a suture by any suitable process, e.g., passing the suture through a solution of the coating composition, past a brush or other coating solution applicator, or past one or more spray nozzles dispensing the coating solution. The suture wetted with the coating solution is subsequently passed through or held in a drying oven for a time and at a temperature sufficient to volatilize and drive off the solvent.

The coating composition can, if desired, contain one or more other components, e.g., dyes, antibiotics, antiseptics, growth factors, anesthetics, anti-inflammatory agents, etc.

While the coating composition herein can be applied to any type of suture, it is essentially intended for application to a braided suture, a preferred type of which is disclosed in U.S. Pat. No. 5,019,093, the contents of which are incorporated by reference herein. The amount of coating composition applied to a braided suture will vary depending upon the structure of the suture, e.g., the number of filaments, tightness of braid or twist, the size of the suture and its composition.

The coating composition herein can be used for both "unfilled" as well as "filled" sutures, the latter designating braided bioabsorbable sutures containing a storage stabilizing material as disclosed in U.S. Pat. Nos. 5,037,429 or 5,051,272, the contents of which are incorporated by reference herein. For an "unfilled" suture, the coating composition can be applied at a level of from about 0.5 to about 4 weight percent or more and preferably from about 1 to about 3 weight percent. Advantageously, the coating composition is applied to the suture prior to application of the storage stabilizing material. For a filled suture, the amount of applied coating composition can range from about 0.2 to as much as about 3 weight percent or more and preferably from about 0.5 to about 2 weight percent. As a practical matter, it is generally preferred to apply the minimum amount of coating composition consistent with good tie-down performance. This level of coating add-on can be readily determined for any particular suture coating system employing routine experimental procedures.

In the case of an unfilled or filled braided suture, prior to application of the coating composition, it can be advantageous to calender the suture in order to improve the uniformity with which the coating composition is laid down upon the suture surface. A calendering operation can also be beneficial when carried out on a coated suture where the suture is to be filled with a storage stabilizing material. In this case, calendering will tend to break up the coating facilitating penetration of the interior spaces of the suture by the storage stabilizing material.

A preferred method for calendering a braided suture and an apparatus for carrying out the method are disclosed in copending U.S. patent application Ser. No. 07/652,939, filed Feb. 8, 1991, the contents of which are incorporated by reference herein. In accordance with Ser. No. 07/652,939, calendering of a braided suture is achieved by applying a compressive force to the suture in a first line or direction generally transverse to the longitudinal direction of the suture, the compressive force being of sufficient magnitude as to flatten the suture in a direction orthogonal to the direction in which the compressive force is applied. Preferably, a

4

second application of compressive force is applied to the suture in a direction generally transverse to that of the first compressive force and transverse to the longitudinal direction of the suture. The second compressive force is substantially equal in magnitude to the first compressive force so that the suture returns to its original cross-sectional configuration.

The apparatus for implementing the foregoing calendering method includes at least one pair of rollers which are biased towards each other to apply a compressive force to the suture as the suture passes between them. Optionally, a second pair of rollers is provided which is oriented at an angle (preferably 90°) to the first pair of rollers and transverse to the longitudinal direction of the suture. Following passage between both the first and second pair of rollers, the suture will have been alternately compressed, or flattened, in a first direction and thereafter in a second direction at an angle to the first direction.

The following examples are illustrative of the absorbable coating composition of this invention, its preparation and sutures coated therewith.

EXAMPLE 1

This example illustrates the preparation of an absorbable suture coating composition in accordance with the invention.

A poly(oxypropylene) glycol of 4,000 average molecular weight (nominal) and a viscosity of from 900-1200 cp, 677 ± 1 g, was introduced into a reactor equipped with a stirrer. Following a minimum 6 hour period of drying the poly(oxypropylene) glycol in a stream of anhydrous nitrogen gas, a previously dried lactide/glycolide copolymer containing 82 mole percent lactide and 18 mole percent glycolide and an inherent viscosity of at least 0.9 when measured in chloroform at a concentration of 0.25 g/dl (prepared as disclosed in U.S. Pat. No. 4,523,591 referred to above), $1,323 \pm 1$ g, was introduced into the reactor. The reactor, which was maintained under a blanket of nitrogen gas, was heated to a temperature of 155°-170° C. Thereafter, 0.4 ± 0.05 g stannous octoate catalyst and 0.4 ± 0.05 g diethylene glycol initiator were added to the reactor, the latter being stirred at a rate of 55-60 rpm. Following a reaction period of 20-25 hours, the reaction product was recovered and residual reactant(s) removed therefrom at elevated temperature and under a pressure not exceeding 10 Torr, the temperature profile being as follows:

1. Ramped to 80° C. at 5° C./hr.
2. Soaked at 80° C. for 1 hr.
3. Ramped to 125° C. at 2.5° C./hr.
4. Soaked at 125° C. for 1-48 hrs.
5. Cooled to $\leq 30^\circ$ C.

The reaction product, which had an inherent viscosity below 0.5 when measured in chloroform at a concentration of 0.25 g/dl, was used as the coating composition in Examples 2 and 3 which follow.

EXAMPLE 2: COMPARATIVE EXAMPLES 1-3

Suture knot security for a coated suture in accordance with this invention (Example 2) and three known types of suture (Comparative Examples 1-3) was evaluated in divided canine fascia (linea alba) using a standard surgeon's knot.

The sutures of Example 2 were size 0 synthetic absorbable braided sutures constructed in accordance with U.S. Pat. No. 5,019,093, and coated with approxi-

5,312,437

5

mately 2.6 percent by weight of suture with the coating composition of Example 1 using the apparatus of Ser. No. 07/652,929, supra, by passing the suture through calender rolls, past a coating head to deposit the desired amount of coating composition in solvent and evaporating the solvent in a drying oven. Thereafter, the coated suture was calendered and filled with approximately 10 weight percent glycerin/calcium lactate in accordance with U.S. Pat. No. 5,037,429 using the calendering and filling apparatus of Ser. No. 07/652,939.

The sutures of Comparative Example 1 were size 0 Vicryl® synthetic absorbable braided sutures from Ethicon Inc. The sutures are believed to be coated with a copolymer of glycolide/lactide with calcium stearate.

The sutures of Comparative Example 2 were size 0 sutures constructed in accordance with U.S. Pat. No. 5,019,093, coated with approximately 1.4 percent by weight of suture with a 50:50 weight ratio copolymer of glycolide/lactide (18:82 mole percent) and poly(oxyethylene) glycol as disclosed in pending U.S. patent application Ser. No. 07/707,437, U.S. Pat. No. 5,123,912, referred to above and filled with approximately 10 weight percent glycerin/calcium lactate in accordance with U.S. Pat. No. 5,037,429. The sutures of Comparative Example 3 were coated and filled in substantially the same manner as in Example 2 employing the same equipment.

The sutures of Comparative Example 3 were the same as the sutures of Comparative Example 2 except that the coating was applied at approximately 3.0 percent by weight of suture.

The knot was configured as a hand tie (two right over left throws plus one left over right throw). The sutures were evaluated in normal abdominal fascia as well as thicker fascia toward the pubis. The results of the testing are set forth below as the number of sutures which held without slipping per total number of sutures tied.

	Normal Fascia	Heavy Fascia
Example 2	4:4	4:6
Comparative Example 1	4:8	3:4
Comparative Example 2	1:3	0:2
Comparative Example 3	1:6	—

These results demonstrate the superior knot security characteristics conferred by the suture coating composition of this invention compared to that obtained with known coating compositions.

EXAMPLE 3; COMPARATIVE EXAMPLES 4-6

Knot run-down for a coated suture in accordance with this invention (Example 3) and three known types of suture (Comparative Examples 4-6) was evaluated by forming a hand tied square knot (right over left throw plus left over right throw) approximately 1 cm from the fascial edge of canine tissue and then running the knot down tightly around the fascial edge.

The sutures of Example 3 were size 3/0 sutures identical in all other respects to the sutures of Example 2 and the sutures of Comparative Examples 4, 5 and 6 were size 3/0 sutures identical in all other respects to the sutures of Comparative Examples 1, 2 and 3, respectively. The results of the testing are set forth below as the number of sutures which ran down and the total number of tries.

6

	Knot Run Down
Example 3	4:6
Comparative Example 4	6:6
Comparative Example 5	3:6
Comparative Example 6	2:6

The test results show that sutures coated with the coating composition of the present invention demonstrate superior run-down characteristics compared to sutures of identical construction which have been coated with the composition disclosed in pending U.S. patent application Ser. No. 07/707,437, filed May 28, 1991, referred to above. Moreover, the properties of the coated suture compare favorably with those of a commercial suture of comparable size.

What is claimed is:

1. A suture coated with a coating composition comprising the product obtained by reacting a mixture of poly(oxypropylene) glycol and lactide/glycolide copolymer.

2. The suture of claim 1 wherein the poly(oxypropylene) glycol possesses a molecular weight of from about 400 to about 6,000.

3. The suture of claim 1 wherein the poly(oxypropylene) glycol possesses a molecular weight of from about 1,000 to about 4,000.

4. The suture of claim 1 wherein the lactide/glycolide copolymer is prepared with L-lactide.

5. The suture of claim 1 wherein the lactide/glycolide copolymer contains from about 90 to about 65 mole percent lactide and from about 10 to about 35 mole percent glycolide.

6. The suture of claim 1 wherein the lactide/glycolide copolymer contains from about 85 to about 70 mole percent lactide and from about 15 to about 30 mole percent glycolide.

7. The suture of claim 1 wherein the lactide/glycolide copolymer prior to reaction with the poly(oxypropylene) glycol possesses a glass transition temperature of at least about 54° C. when measured by differential scanning calorimetry at 20° C./min and an inherent viscosity of at least about 0.9 when measured in chloroform at a concentration of 0.25 g/dl.

8. The suture of claim 7 wherein the composition following reaction possesses an inherent viscosity of less than about 0.9 when measured in chloroform at a concentration of 0.25 g/dl.

9. The suture of claim 7 wherein the composition following reaction possesses an inherent viscosity of less than about 0.5 when measured in chloroform at a concentration of 0.25 g/dl.

10. The suture of claim 1 wherein the weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer is from about 4:1 to about 1:4.

11. The suture of claim 1 wherein the weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer is from about 2:1 to about 1:2.

12. The suture of claim 1 wherein the composition following reaction possesses an inherent viscosity of less than about 0.9 when measured in chloroform at a concentration of 0.25 g/dl.

13. The suture of claim 1 wherein the composition following reaction possesses an inherent viscosity of less than about 0.5 when measured in chloroform at a concentration of 0.25 g/dl.

5,312,437

7

14. The suture of claim 1 wherein the poly(oxypropylene) glycol is reacted with the lactide/glycolide copolymer in the presence of an initiator.

15. The suture of claim 14 wherein the initiator is a glycol.

16. The suture of claim 15 wherein the glycol is diethylene glycol.

17. The suture of claim 1 wherein the suture is a synthetic multifilament suture.

18. The suture of claim 1 wherein the suture is an absorbable synthetic multifilament suture.

19. The suture of claim 1 exhibiting improved knot tie-down and/or knot security characteristics compared with the knot tie-down and/or knot security characteristics of the same suture coated with an equivalent amount of an absorbable composition obtained by reacting a poly(oxyethylene) glycol with a mixture of lactide and glycolide and/or lactide/glycolide copolymer.

20. A method of improving the knot tie-down and/or knot security characteristics of a suture which comprises coating the suture with an absorbable composition comprising the product obtained by reacting a mixture of poly(oxypropylene) glycol and lactide/glycolide copolymer.

21. The method of claim 20 wherein the poly(oxypropylene) glycol possesses a molecular weight of from about 400 to about 6,000.

22. The method of claim 20 wherein the poly(oxypropylene) glycol possesses a molecular weight of from about 1,000 to about 4,000.

23. The method of claim 20 wherein the lactide/glycolide copolymer is prepared with L-lactide.

24. The method of claim 20 wherein the lactide/glycolide copolymer contains from about 90 to about 65 mole percent lactide and from about 10 to about 35 mole percent glycolide.

25. The method of claim 20 wherein the lactide/glycolide copolymer contains from about 85 to about 70 mole percent lactide and from about 15 to about 30 mole percent glycolide.

8

26. The method of claim 20 wherein the lactide/glycolide copolymer prior to reaction with the poly(oxypropylene) glycol possesses a glass transition temperature of at least about 54° C. when measured by differential scanning calorimetry at 20° C./min and an inherent viscosity of at least about 0.9 when measured in chloroform at a concentration of 0.25 g/dl.

27. The method of claim 26 wherein the composition following reaction possesses an inherent viscosity of less than about 0.9 when measured in chloroform at a concentration of 0.25 g/dl.

28. The method of claim 26 wherein the composition following reaction possesses an inherent viscosity of less than about 0.5 when measured in chloroform at a concentration of 0.25 g/dl.

29. The method of claim 20 wherein the weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer is from about 4:1 to about 1:4.

30. The method of claim 20 wherein the weight ratio of poly(oxypropylene) glycol to lactide/glycolide copolymer is from about 2:1 to about 1:2.

31. The method of claim 20 wherein the poly(oxypropylene) glycol is reacted with the lactide/glycolide copolymer in the presence of an initiator.

32. The suture of claim 31 the initiator is a glycol.

33. The suture of claim 32 wherein the glycol is diethylene glycol.

34. The method of claim 20 wherein the suture is a synthetic multifilament suture.

35. The method of claim 20 wherein the suture is an absorbable synthetic multifilament suture.

36. The method of claim 20 wherein the resulting coated suture exhibits improved knot tie-down and/or knot security characteristics compared with the knot tie-down and/or knot security characteristics of the same suture coated with an equivalent amount of an absorbable composition obtained by reacting a poly(oxyethylene) glycol with a mixture of lactide and glycolide and/or lactide/glycolide copolymer.

* * * * *

45

50

55

60

65

EXHIBIT 38

Knotting and Handling Characteristics of Coated Synthetic Absorbable Sutures

GEORGE T. RODEHEAVER, PH.D.,^{1,2} JOHN G. THACKER, PH.D.,³ JOHN OWEN, B.S.,³
MARK STRAUSS, M.S.,³ TOM MASTERSON, B.A.,²
AND RICHARD F. EDLICH, M.D., PH.D.²

²Department of Plastic Surgery, University of Virginia Medical Center, Charlottesville, Virginia 22908, and

³Department of Mechanical Engineering, University of Virginia, Charlottesville, Virginia 22908

Submitted for Publication January 6, 1983

The purpose of this study was to evaluate the knotting and handling characteristics of the new coated synthetic absorbable sutures. When compared to the coated polyglactin 910 sutures, the coated polyglycolic acid sutures displayed a lower coefficient of friction, encountered less tissue drag forces, and exhibited less flexural rigidity. In the case of sizes 0, 2-0, and 3-0 coated polyglycolic sutures, knot security was achieved with one less throw than with similar sizes of coated polyglactin 910 sutures. On the basis of these comprehensive mechanical performance tests, the knotting and handling characteristics of the coated polyglycolic acid sutures were judged to be superior to that of the coated polyglactin 910 sutures.

INTRODUCTION

As an alternative to gut sutures, two new synthetic absorbable sutures have been introduced for wound closure. These two sutures are very similar in their physical and chemical configuration. One suture is braided from filaments of polyglycolic acid while the other is braided from a copolymer of glycolic acid (90%) and lactic acid (10%). In most clinical situations these synthetic sutures have proven to be superior to gut sutures with respect to strength retention, tissue reactivity, incidence of postoperative complications, and influence on wound healing [3]. However, the surfaces of these synthetic absorbable sutures display a high coefficient of friction that makes tying difficult. When tying these sutures, surgeons may find themselves frustrated by their inability to set or advance a two-throw square knot. When the two-throw knot locks prematurely, the surgeon will usually break the suture as he tries to advance the knot. The rough suture surface also causes the suture to drag through tissue [1] making it difficult to adjust tension on a continuous running surface.

Recently, the surfaces of these synthetic sutures have been coated to decrease their coefficient of friction and improve their handling characteristics. A comprehensive analysis of the mechanical performance of these coated synthetic sutures was conducted. This critical analysis of sutural performance determined the number of throws needed to achieve knot security, the expected slippage of the knot in its secure configuration, the coefficient of friction, and tissue drag as well as the suture's flexural rigidity and memory.

MATERIALS AND METHODS

Three types of sutures were evaluated in this study. Dexon "S" (Davis & Geck, Wayne, N. J.) is a braided polyglycolic acid suture without coating. Dexon Plus (Davis & Geck) has the same construction as Dexon "S" but is treated with an absorbable surface lubricant, Poloxamer 188. Coated Vicryl (polyglactin 910) (Ethicon, Inc., Somerville, N. J.) sutures are braided filaments of the copolymer of polyglycolic acid and lactic acid which have been coated with an absorbable mixture of calcium stearate and a copolymer of lactic acid (65%) and glycolic acid (35%). The su-

¹ To whom reprint requests should be addressed.

tures were obtained from individual suppliers and tested as received from their individual sterile packages. The sutures evaluated were in sizes 0, 2-0, 3-0, 4-0, and 5-0. The diameter of each suture was measured without compression. The suture was mounted under a microscope and its magnified image was displayed on a calibrated television screen and its thickness measured.

KNOT PERFORMANCE

The mechanical performance of a knotted suture can be measured, in part, by its knot-holding strength, its knot slippage, and the number of throws required to complete a knot that will reach break [5]. In this study, reproducible knots were mechanically tied at a constant rate of loading with predetermined tension using an Instron Tensile Tester. Tying the knot under known tensions eliminates the variability encountered with hand-tied knots. The tying of a reproducible square knot ($1 = 1$) was accomplished by forming the knot without subjecting its ears to any appreciable tension. The formed knot was then secured utilizing a tension equivalent to $85 \pm 5\%$ of the specific knot-holding tension. This tension is similar to that utilized by a surgeon who carefully snugs each throw tightly together.

The tension was applied to the knot using the Instron Tensile Tester. One ear of the knot was secured to the upper jaw of the tensile tester while the other ear of the knot was attached to a weight equivalent to the predetermined tension to be used to tie the knot. The weight was lifted off the lower jaw by the attached suture at a rate of 2 mm/min. The total load remained on the knot for 10 sec to complete the tying of the first two throws of the knot. When additional throws were being tested, the procedure was repeated for each throw. Each additional throw was formed so that its configuration was square ($1 = 1 = 1 \dots$) in reference to the previous throw. No tension was placed on the patient's side of the knot.

After completing the knot, the loop was divided at its midpoint. The loop ends were

then positioned in the jaws of the tensile tester so that the test section was taut and that the knot was centered in the 51-mm jaw separation. The knot was then loaded until knot break at an extension rate of 20 mm/min. The knot-holding capacity was recorded as the maximum load value on the load extension curve before knot breakage and/or infinite slippage.

Slippage for all tests was determined at the level of the 95% confidence limit for knot-holding capacity. At this level the slippage was obtained by subtracting the mean elongation value of sutures without a knot subjected to the desired load from the mean elongation value of knotted sutures under the same load.

ANALYSIS OF KNOT SECURITY

A secure knot was defined as a knot that went to knot break without slipping more than 3.0 mm. The minimum load at which 95% of the knotted sutures can be expected to survive without breaking was defined as the 95% knot break load (KBL_{95}). KBL_{95} was determined from the number of samples tested, the mean knot break load (\overline{KBL}), and the standard deviation (SD_{KBL}). Due to the small number of samples tested (10 to 12) for each suture size, the data were assumed to follow the form of a "t" distribution. Using tabulated "t" values, KBL_{95} was determined by the equation:

$$KBL_{95} = \overline{KBL} - t(SD_{KBL}).$$

At KBL_{95} , mean knot slippage (\overline{KS}) was determined from the difference between mean elongation of the sutures without a knot (E_{wo}) and mean elongation of the sutures with a knot (E_w):

$$\overline{KS} = E_w - E_{wo},$$

where $E_w \geq E_{wo}$.

The maximum slippage that would be expected to occur in 95% of the knotted sutures at KBL_{95} was defined as MKS_{95} and was determined in a similar manner to KBL_{95} by using the formula

$$MKS_{95} = \overline{KS} + t(SD_{KS}).$$

After (BL) and ture, the l terminated

where BL of unknot out break

Knot e ficiently t suture ma the break knot effici can be de

CC

The kn is depend operating strands. In tional for was meas The coeff the ratio strand acr strand wa experimer

Anothe the suture the suture a standard pared para On each s lines was c pair of lor series of p mm. For swaged to Dexon; K and suture the dermis tance of 3

After determining the mean break load (\overline{BL}) and standard deviation of unknotted suture, the lower 95% confidence limit was determined using the formula

$$BL_{95} = \overline{BL} - t(SD_{BL}),$$

where BL_{95} = the minimum load that 95% of unknotted sutures can be exposed to without breaking.

Knot efficiency is an indication of how efficiently the knot utilizes the strength of the suture material. A knot that did not reduce the breaking value of a suture would have a knot efficiency of 100%. Thus knot efficiency can be determined by

$$\text{knot efficiency} = \frac{KBL_{95}}{BL_{95}}.$$

COEFFICIENT OF FRICTION

The knotting profile of all suture materials is dependent in part on the frictional forces operating at the surface of the overlapping strands. In this study, an estimate of the frictional forces encountered during knot tying was measured using the Instron Tensile Tester. The coefficients of friction was calculated from the ratio of forces needed to pull one suture strand across itself at a right angle when one strand was under a constant load. For this experiment size 3-O sutures were evaluated.

TISSUE DRAG

Another aspect of frictional forces acting at the suture surface is the force required to pull the suture through tissue. In this experiment a standard model involving the surgically prepared paravertebral skin of the rabbit was used. On each side of the spine a pair of parallel lines was drawn that were 30 mm apart. Each pair of longitudinal lines was connected by a series of perpendicular lines separated by 10 mm. For this experiment, size 3-O sutures swaged to straight cutting needles (CS-1 for Dexon; KS for Vicryl) were used. The needle and suture were passed transversely through the dermis beneath one of the lines for a distance of 30 mm. After exiting from the skin,

the needle reentered the skin 10 mm caudad to its exit point and was passed back through the dermis for another 30 mm until it exited 10 mm caudad to its original point of entrance. The needle was then attached to a continuous drive strain gauge that recorded the force necessary to pull the suture through the tissue at a constant rate of 88 mm/min. The mean pull through force was determined from the load curve.

FORCE REQUIRED TO STRAIGHTEN COILED SUTURES

Packaging of the suture strands requires that the suture be folded several times. When the suture material has memory, the suture remains kinked after removal from its package. Stretching the suture under a load such as a quick jerk sometimes erases this memory. In this experiment the minimum load required to erase the memory was determined. After removal of the suture strand from its package a loop was tied in the end of the size 3-O suture. The loop was placed over a known weight and the weight lifted at a rate of 20 mm/min until the weight was hanging free. The suture was exposed to the load for 15 sec before being released. If the suture still remained kinked, more weight was added and the process was repeated until the suture hung straight immediately after removing the weight. This process was repeated with 10 samples of each suture.

STIFFNESS

Suture stiffness is an important parameter that significantly influences the handling characteristics of the suture. An indication of suture rigidity was obtained by calculating the product of the suture area moment of inertia I and the modulus of elasticity of the material (E).

The modulus of elasticity E was determined from the slope of the tangent drawn to the load extension curve at a load of 17.68 N. 17.68 N was the KBL_{95} for 3-O coated polyglactin 910 and was lower than that for

either of the polyglycolic acid sutures. The assumption was made that the suture materials were homogeneous throughout their cross-sectional area. The load extension curves were obtained from 50-mm gauge-length samples that were loaded at a constant extension rate of 20 mm/min. The area moment of inertia (I) calculation assumed the sutures had a round cross-sectional area and

$$I = \frac{\pi D^4}{64},$$

where D = suture diameter.

Thus stiffness or the product of E and I results from the reduced equation:

$$\text{stiffness} = EI = \frac{(K)GD^2}{16},$$

where

E = modulus of elasticity (MPa),

I = area moment of inertia (mm^4),

K = slope of the tangent drawn to the load extension curve at KBL_{95} (N/mm),

G = gauge length (mm), and

D = suture diameter (mm).

RESULTS

The mechanical performance data for the three synthetic absorbable sutures are presented in Table 1. For the uncoated polyglycolic acid suture, the number of throws required to form a square knot that fails at knot break with slippage equal to or less than 3 mm was two throws ($1 = 1$) regardless of suture size. When this suture was coated, knot security was only accomplished with a square knot construction comprised of four throws ($1 = 1 = 1 = 1$) for all suture sizes tested. In the case of O, 2-O, and 3-O coated polyglactin 910 sutures, five throws square ($1 = 1 = 1 = 1 = 1$) were necessary to achieve knot security. A four-throw square knot construction ($1 = 1 = 1 = 1$) was required for knot security for the smaller-size coated polyglactin 910 sutures (4-O and 5-O).

Coating the polyglycolic acid suture did not significantly alter its knot-break strength. However, the breaking strength of unknotted, uncoated polyglycolic acid sutures was unusually higher than that of the unknotted, coated polyglycolic acid sutures. This disproportionate increase in the breaking strength

TABLE 1
KNOT PERFORMANCE VALUES

Type of suture	Suture size	Suture diameter (μm)	Knot security (No. throws)	KBL ₉₅ ^a (N)	MKS ₉₅ ^a (N)	BL ₉₅ ^a (N)	Knot ^a efficiency (%)
Uncoated polyglycolic acid	0	482 \pm 2	2	4576	3.0	8926	51
	2-0	453 \pm 5	2	3802	3.0	6468	59
	3-0	343 \pm 3	2	2055	2.9	3873	53
	4-0	284 \pm 2	2	1329	1.6	2514	53
	5-0	192 \pm 2	2	755	3.0	1403	54
Coated polyglycolic acid	0	527 \pm 15	4	4451	2.4	7259	61
	2-0	450 \pm 6	4	3536	2.0	6163	57
	3-0	302 \pm 4	4	1962	2.2	2931	67
	4-0	302 \pm 7	4	1408	2.2	2084	69
	5-0	227 \pm 5	4	801	1.9	1469	55
Coated polyglactin 910	0	469 \pm 8	5	3742	3.0	7793	48
	2-0	394 \pm 2	5	2816	3.0	6127	46
	3-0	293 \pm 1	5	1768	1.2	3714	48
	4-0	235 \pm 1	4	1169	1.9	2512	46
	5-0	179 \pm 1	4	625	2.3	1398	45

* See text for definitions: KBL, knot break load; MKS, maximum knot slippage; BL, unknotted break load.

of the unk
pared to th
for the incr
sutures. Th
knot efficie
polyglycoli
for the poly
of knot bre
910 suture:
ameter. W
were meas
ameters of
uniformly
and uncona

Coating effects on the coefficient of friction for the uncoated suture were lower, that of the coated suture. These *in vivo* measurements of the suture required to pull the suture through the tissue compared to the uncoated suture. This difference was not significantly altered by the coating (3.04 ± 0.14 N vs. 3.18 ± 0.14 N).

Para

Coefficient
Tissue drag
Stiffness (N
Straighteni

of the unknotted, uncoated suture as compared to that of the coated suture accounts for the increased knot efficiency of the coated sutures. The knot-break strength as well as knot efficiency for the coated and uncoated polyglycolic acid sutures was greater than that for the polyglactin 910 sutures. This low level of knot break strength for coated polyglactin 910 sutures is due in part to their smaller diameter. When identically labeled suture sizes were measured without compression, the diameters of the polyglactin 910 sutures were uniformly smaller than those of the coated and uncoated polyglycolic acid sutures.

Coating the sutures had other measurable effects on their handling characteristics (Table 2). The coatings reduced the frictional forces encountered when the surface of a specific suture was drawn across itself. In size 3-O, the coefficient of friction for coated polyglycolic acid sutures was significantly less than that for the uncoated suture. The coefficient of friction for the coated polyglycolic acid suture was lower, but did not differ significantly from that of the coated polyglactin 910 sutures. These *in vitro* studies correlated with the *in vivo* measurement of the force required to pass the sutures through tissue. The mean force required to pull uncoated polyglycolic acid suture through tissue was 4.97 ± 0.54 N as compared to a tissue drag force of only 0.61 ± 0.14 N for the coated polyglycolic acid suture. This low level of tissue drag encountered with coated polyglycolic acid sutures was significantly ($P < 0.001$) less than that encountered by the coated polyglactin 910 sutures (3.04 ± 0.31 N).

Other interesting differences between the handling characteristics of these sutures were noted. The rigidity of the coated polyglactin 910 sutures was the greatest, followed by the uncoated polyglycolic acid sutures and then the coated polyglycolic acid sutures. The stiffness of the polyglactin 910 sutures was also associated with considerable resistance to straightening. The load required to straighten coiled polyglactin 910 sutures was significantly greater than that needed for coiled polyglycolic acid sutures. The forces required to straighten coiled polyglycolic acid coated and uncoated sutures did not differ significantly.

DISCUSSION

The surfaces of synthetic absorbable sutures, until now, exhibited a high coefficient of friction which made them difficult to tie [4]. In addition, their rough surfaces resisted easy passage through tissue [1] which complicated wound closure with a continuous suture. To improve their handling characteristics, coatings were applied to their surfaces to alter their mechanical performance. These coatings serve as lubricants that reduce the frictional forces on the suture surface. Using these new coated synthetic sutures the surgeon now can easily advance a two-throw knot to approximate the wound edges. Once the tissue is meticulously coapted, the surgeon can then tie the additional throws required for knot security. In addition, the coatings have reduced the force required to pull the suture through the tissue making passage of a running coated suture considerably easier. When

TABLE 2
HANDLING CHARACTERISTICS OF SUTURES

Parameter	Suture (3-O)		
	Uncoated polyglycolic acid	Coated polyglycolic acid	Coated polyglactin 910
Coefficient of friction	0.1907 ± 0.0077	0.1296 ± 0.0062	0.1362 ± 0.0063
Tissue drag (N)	4.97 ± 0.54	0.61 ± 0.14	3.04 ± 0.31
Stiffness ($N\ m^2 \times 10^6$)	1.84	1.14	2.41
Straightening force (N)	6.37	7.84	14.71

for the
are pre-
polygly-
rows re-
s at knot
s than 3
ss of su-
ed, knot
a square
r throws
ested. In
polyglacti-
= 1 = 1
knot se-
struction
t security
n 910 su-

re did not
strength.
unknotted.
as un-
unknotted,
is dispro-
g strength

Knot
efficiency
(%)

51
59
53
53
54

6.
57
67
69
55

48
46
48
46
45

break load.

comparing the tissue drag encountered by the two coated synthetic sutures in our study, coated polyglycolic acid sutures produced significantly less frictional forces during tissue passage than did coated polyglactin 910.

In light of these advantages, a potential shortcoming of these coatings must be considered. Since a greater number of throws are required to reach knot security with coated sutures than with the uncoated suture, wound closure with coated sutures will involve a larger amount of suture material. This increase in suture material damages host defenses and invites the development of infection [2]. The magnitude of this increase in suture material for sizes 0, 2-0, and 3-0 is less for coated polyglycolic acid sutures than for coated polyglactin 910 since knot security with the coated polyglycolic acid sutures is achieved with one less throw.

Those surgeons who try to limit the amount of suture material used for wound closure can still resort to the use of uncoated polyglycolic acid sutures in which knot security can be achieved with only two throws. In addition to reducing the risk of infection, this parsimonious use of uncoated suture should decrease the length of the operation. This alternative is not available for the polyglactin 910 sutures since the uncoated suture is no longer commercially available.

The coated and uncoated polyglycolic acid sutures have other special handling characteristics that the surgeon will find attractive. They are supple sutures that can be easily straightened after removal from the package. In contrast, the coated polyglactin 910 sutures are stiff and possess a memory that responds only to forces that approach the breaking strength of the suture. The implications of this sutural rigidity of polyglactin 910 sutures are

several. As the surgeon attempts to straighten this coiled suture, he may break the suture. Furthermore, knots constructed with a stiff suture have a tendency to become untied unless each throw is carefully snugged upon the preceding throw. The cause of the extreme flexural rigidity of the polyglactin suture is uncertain. It may be due either to its composition, construction, or the coating material. Since the uncoated polyglactin 910 suture is not commercially available, the latter hypothesis could not be tested in this study.

While this study focused on the performance of the synthetic absorbable sutures at surgery, the influence of tissue implantation on knot performance remains to be studied. It is hoped that the *in vitro* knot security of the coated and uncoated synthetic sutures will persist in the wounded tissue. This supposition is presently being examined in animal models and will be the subject of a future report.

REFERENCES

1. Apt, L., and Henrick, A. "Tissue-drag" with polyglycolic acid (Dexon) and polyglactin 910 (Vicryl) sutures in strabismus surgery. *J. Ped. Ophthalmol.* 13: 360, 1976.
2. Edlich, R. F., Tsung, M. S., Rogers, W., Rogers, P., and Wangenstein, O. H. Studies in the management of the contaminated wound. I. Techniques of closure of such wounds with a note on a reproducible model. *J. Surg. Res.* 8: 585, 1968.
3. Laufman, H., and Rubel, T. Synthetic absorbable sutures. *Surg. Gynecol. Obstet.* 145: 597, 1977.
4. Rodeheaver, G. T., Thacker, J. G., and Edlich, R. F. Mechanical performance of polyglycolic acid and polyglactin 910 synthetic absorbable sutures. *Surg. Gynecol. Obstet.* 153: 835, 1981.
5. Thacker, J. G., Rodeheaver, G., Moore, J. W., Kauzlarich, J. J., Kurtz, L., Edgerton, M. T., and Edlich, R. F. Mechanical performance of surgical sutures. *Amer. J. Surg.* 130: 374, 1975.

Hear
at

G.

In stu
the majo
is the m
various
sampling
report t
techniqu
into the
which al

Ten-d
were an
ously de
mM⁺Na⁺
acid-Tr
liter), we
kg, direc
fat emul
infused a
was admi
heart wa
butterfly
of the st
space at
chest wa
passing t
was expe
air embol
NaCl be
not fixed
contracti
allow blo
contami
needle w

EXHIBIT 39

Orthocord

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI094378

It Handles Better!

Q. How can it be as strong but less stiff?

A. PDS is less stiff than HMWPE

A. 50% less HMWPE (than FiberWire™) with PDS core (vs. FiberWire PE core)

A. ORTHOCORD is braided with 16 carriers

⇒ Smaller bundles: More flexible

⇒ 16 bundles in a **balanced fiber bundle matrix**



Q. How might this impact handling?

A. Less memory/kick back ⇒ Tighter Knot ⇒ Lower Profile?

A. Coated with Ethicon's proprietary **NVC coating** for improved slide ability and enhanced knot tying characteristics (e.g. knot slide)

Q. **Can improved handling result in fewer knots?**

EXHIBIT 40

Completion Report for Protocol # ST-98053
Protocol for the Development of NVC coating on PanacrylTM suture material

Introduction

The purpose of coating the Panacryl braided suture is to provide the suture with good handling properties. These properties are typically evaluated using performance tests such as knot slide, suture roughness, and knot security tests. It has also been shown that some coatings can have an affect on the knot tensile properties of a suture, actually increasing the knot strength.

The protocol for which this completion report is written, evaluated the "braid-in-braid" Panacryl suture according to the aforementioned tests. The coating material used was NVC(90/10 Caprolactone/Glycolide) in Ethyl Acetate. Three unique braid lots were evaluated. One lot was coated at coating levels from 2% to 7% (wt/wt) with the remaining two lots coated at 4%-6% (wt/wt). Analytical testing was performed on the non-sterile unannealed coated braid to determine the amount of coating on the braid (add-on).

Materials and Methods

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

Three lots of Panacryl size one material were obtained from the Somerville textile group (lot #'s L263BSH, L265BSH, and L266BSH). Lot # L263BSH was coated using 2% through 7% solutions and lots L265BSH and L266BSH were coated using 4% through 6% coating solutions. The coating run summary sheet is shown in Exhibit 1. All materials were coated using the Somerville research coating line dip coating head (identical to the Cornelia Vicryl production dip coating head) and run at 264 ft/min with a

DePuy Mitek, Inc v. Arthrex Inc.
C.A. No.04-12457 PBS
DMI060231

drying tunnel temperature of 120°F. Exhibit 2 describes the rationale for the drying tunnel temperature for Panacryl. The materials were then rack annealed and post pliabilized. Material of sufficient quantity to perform all non sterile testing was separated out and balance of materials was sent through "D" specials for winding, packaging and sterilization. The material was wound in single strand put up and foiled with blank top stock, open vent. The material was exposed to the primary EtO sterilization cycle "F" and secondary sterilization cycle "J". A sample work order for "D" specials is attached as Exhibit 3. The sterile materials were then forwarded to CPC for knot slide, knot security and suture roughness evaluation. The knot slide and suture roughness tests were performed on the lowest coating concentration and if the material did not pass the next higher concentration would be tested. If the material passed at the lowest concentration, no more knot slide or suture roughness testing is required. If the material has acceptable knot slide and suture roughness at a lower coating concentration, the material coated at higher concentrations will have acceptable knot slides and suture roughness, because an increase in coating on the braid can only help the material to slide against itself. This would improve the knot slide and suture roughness results. The knot security testing was performed on the highest coating concentration and if the material did not pass, the next lower concentration would be tested. If the material passed at the highest concentration, no more knot security testing is required. If the material has acceptable knot security at a higher coating concentration, the material coated at lower concentrations will have acceptable knot security, because a decrease in coating on the braid can only help to secure the knot.

Sterile materials were also evaluated for diameters and tensile strength by Suture technologies.

DePuy Mitek, Inc v. Arthrex Inc.
C.A. No.04-12457 PBS
DMI060232

Results

A summary of results for the Suture technology testing (diameters and tensile) are shown as Appendix 1. All non-sterile samples, with the exception of the material coated at 2%, exceeded the raw material minimum requirements for straight and knot tensile strength. The average straight tensile strength ranged from 23.49 to 25.02 lbs., and size 1 has a

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

minimum average requirement of 20.04 lbs. The average knot tensile strength ranged from 11.87 to 12.70 lbs., and size 1 has a minimum average requirement of 11.79 lbs. The non-sterile material diameters were in the range of 21.0 to 21.6 mils, and are also within the material average requirements range of 19.68 to 22.25 mils. The sterile materials all exceeded the finished goods minimum requirements for straight and knot tensile strength. The sterile material diameters were also within the material requirements with diameters in the range of 20.9 to 21.7 mils. The test results from the knot slide tests are attached as Appendix 2. The three lots were tested at the lowest coating concentrations (L263@2%, L265@4%, and L266@4%) and all had acceptable knot slide of 10 slides out of 10 attempts. The knot security test results are attached as Appendix 3. The three lots were tested at the highest coating concentrations (L263@7%, L265@6%, and L266@6%) and all three lots were secure at four throws. The suture roughness test results are attached as Appendix 4. The suture roughness on all three lots was acceptable.

The coating add on test results are shown as Appendix 5. The coating add on values ranged from 0.48% to 1.83% (weight of coating/weight of braid). The braid with the 0.48% add on (coated with 2% coating solution) had acceptable knot slide and the braid with the 1.83% add on (coated with 7% coating solution) had four throw knot security.

Discussion

The test results from the straight and knot tensile testing document that the braid meets the USP requirements for size 1, with regards to tensile strength. The diameter range for size 1 Panacryl is 19.68 to 22.25 mils. The diameter range recorded in this study was from 20.9 mils to 21.7 mils, which is within the required range.

The knot slide test results document the functionality of the coating at the lower coating concentrations of 2% and 4%. All tested specimens satisfied the 10/10 knot slide requirement. The knot slide forces were documented for all specimens tested.

The knot security test results document the functionality of the coating at the higher coating concentrations of 6% and 7%. All tested specimens satisfied the 0/20 slip through, 18-20/20 knot secured and 0-2/20 slip break requirements at four throws.

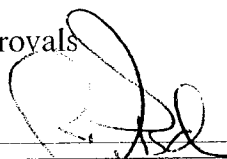
The suture roughness test results are provided for informational purposes. There is no suture roughness requirement, however, the Panacryl test results were comparable to values typical for size 1 coated Vicryl™.

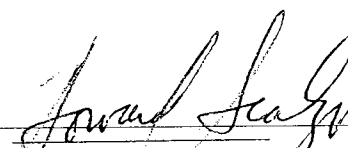
The coating concentrations used in this study ranged from 2% to 7%. All three lots were coated at 4, 5, and 6% coating solution. It was documented that the Panacryl material functioned when coated with solutions from 2% through 7%. To provide a conservative range of target coating concentrations the outer ends of the coating concentrations will be moved in to 4% to 6%, with a target (nominal) of 5%. The add on range will be determined by using the add ons from one concentration away from the 4% - 6% target range (3% and 7%) to allow for manufacturing ability.

Conclusions

From the results of this study it can be concluded that the Panacryl™ suture meets or exceeds the requirements of this study. The Panacryl™ material was functional when coated with NVC coating in Ethyl Acetate at coating solutions concentrations of 2% to 7% (wt/wt) and coating add ons of from 0.48% to 1.83% (wt/wt). It is therefore recommended that the coating solution range be from 4% to 6% with a nominal coating concentration of 5%. The add on ranges recommendation is from 0.7% to 1.8%.

Approvals


Jerry Fischer
Engineering Fellow


Howard Scalzo
Senior Engineer

DePuy Mitek, Inc v. Arthrex Inc.
C.A. No. 04-12457 PBS
DMI060234

CONFIDENTIAL -
NON-PATENT
PROSECUTION COUNSEL ONLY

EXHIBIT 41

Confidential Deposition of:
Gary B. McAlister

December 22, 2005

Page 1

1 IN THE UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3 C.A. No. 04-12457 PBS

4 * * * * *

ORIGINAL

5 DePUY MITEK, INC.,

6 Plaintiff

7 v.

8 ARTHREX, INC., a Delaware

9 corporation,

10 Defendant

11 * * * * *

12 VOLUME I

13 PAGES 1-197

14

15 DEPOSITION OF GARY B. McALISTER, a
16 witness called on behalf of the Defendant,
17 pursuant to the Federal Rules of Civil
18 Procedure, before Jessica L. Williamson,
19 Registered Merit Reporter, Certified
20 Realtime Reporter and Notary Public in and
21 for the Commonwealth of Massachusetts, at
22 the Four Points Sheraton, 1125 Boston
23 Providence Turnpike, Norwood, Massachusetts,
24 on Thursday, December 22, 2005, commencing
25 at 8:59 a.m.

1 A. I've read plastics books so that I'm aware
2 of it.

3 Q. What plastics books?

4 A. Plastic reference books. I don't recall the
5 title.

6 MR. FALKE: Chuck, we've been going
7 about an hour. Do you want to take a break?

8 MR. SABER: Sure, any time you
9 want.

10 (Recess taken.)

11 Q. We were talking about materials -- your
12 information on the materials in sutures, and
13 we were talking about Orthocord. Is
14 Orthocord a coated product?

15 A. Yes.

16 Q. Okay. Do you know what coating is on that?

17 A. No.

18 Q. Do you know why there's a coating on the
19 product?

20 A. Yes.

21 Q. Okay. Why is there a coating on the
22 product?

23 A. It makes the handling much better, is my
24 understanding that that's why coatings are
25 put on there. It'll tie better, it'll slide

1 better. They call it the hand, it improves
2 the hand of the suture. Can I put my jacket
3 on? It's cold in here.

4 **Q. That's absolutely fine.**

5 MR. FALKE: Why don't we go off the
6 record for one second.

7 (Discussion off the record.)

8 MR. SABER: Could you read back his
9 last answer?

10 (Record read.)

11 **Q. What do you mean, "they call it the hand"?**

12 A. That's the way -- that's the term that's
13 been described to me as a term that relates
14 to the handling and how it feels in the
15 hands of a surgeon. I think that's what it
16 refers to.

17 **Q. Anything else for purposes of coating, why
18 it's coated?**

19 A. Ethicon just released a coating -- a suture
20 that has antimicrobials embedded in the
21 coating, so it could be a carrier for
22 antimicrobials.

23 **Q. Okay. Anything else?**

24 A. No.

25 **Q. Does coating have any role, from your**

EXHIBIT 42

1

2

UNITED STATES DISTRICT COURT

3

DISTRICT OF MASSACHUSETTS

4

C.A. No. 04-12457 PBS

5

-----x

6

DePUY MITEK, INC.,

7

A Massachusetts Corporation,

8

Plaintiff,

9

v.

10

ARTHREX INC.,

11

A Delaware Corporation,

12

Defendants.

13

-----x

14

15

* * *CONFIDENTIAL* * *

16

DEPOSITION OF ILYA KOYFMAN

17

Somerset, New Jersey

18

February 22, 2006

19

20

Reported by:

21

MARY F. BOWMAN, RPR, CRR

22

JOB NO.: SE232

23

24

25

1 KOYFMAN - Confidential

2 A. Yes.

3 Q. Did you prepare this document?

4 A. Yes.

5 Q. What is it?

6 A. It's a product development strategy
7 for Orthocord.

8 Q. Can you turn to page DMI 082160.

9 A. OK.

10 Q. I want to ask you a little bit about
11 the -- what comes under the heading "braiding
12 through coating," et cetera. Particularly the
13 last paragraph on the page. The sentence that
14 says, "Coating selection depends on maintaining a
15 fine balance between suture tie-down and knot
16 security."

17 A. Um-hm.

18 Q. What did you mean by that sentence?

19 A. The prime reason for applying coating
20 is to have a good tie-down, good tie-down and
21 tissue passage and so forth. When you apply
22 coating, you might affect other properties. So
23 that's what I meant, you have to have a balance.

24 Q. The other properties being knot
25 security?

EXHIBIT 43

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Expert Report of Dr. Matthew Hermes

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post

apparent to one of ordinary skill in the art and that patent specifications need not be as detailed as production specifications.

D. Actual Reduction to Practice

27. I understand that invention requires a conception and reduction to practice. I understand that conception is the formulation of an idea in one's mind of a definite and permanent idea. I further understand that actual reduction to practice typically occurs when the claimed invention is constructed and evaluated sufficiently to know that it will work for its intended purpose.

IV. Claim Construction

28. As mentioned above, I understand that the first step in an invalidity analysis is to determine the meaning of the claims. I understand that the Court will determine the meaning of the claim terms in the 446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

"PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

"Consisting essentially of" – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

“Direct intertwining contact” means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

“Volume fraction of the first set of yarns in the braided sheath and core” means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

I reserve the right to modify my opinion should the Court determine the meaning of the claims are different than the above constructions.

V. Materials Considered in Forming My Opinions

29. In forming my opinions, I have considered the 446 Patent, its file history, and the reports of Dr. Debi Prasad Mukherjee and John F. Witherspoon, and Peter Dreyfuss's, Brian Hallet's, and Dr. Mark Steckel's, and Mr. Donald Grafton's deposition testimony.

A list of the documents that I used in forming my opinions is set forth in Ex. 16.

VI. Claims 1, 2, 8, 9, & 12 of the 446 Patent Are Not Invalid Over the References Discussed by Dr. Mukherjee

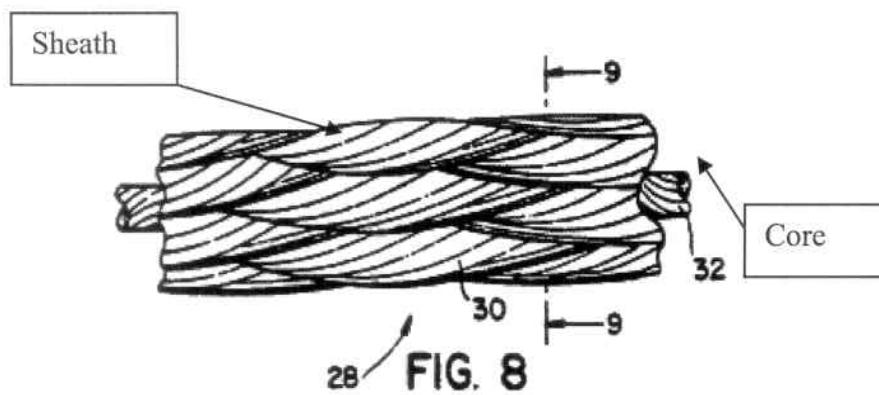
A. The Level Of Ordinary Skill In The Art

30. I understand that Dr. Mukherjee has opined that a person of ordinary skill in the art, “in February 1992, had an undergraduate degree in engineering or science and several years (*e.g.*, approximately 3-5) experience with manufacturing and/or processing of fibers and sutures which can be used for biomedical applications.” (Mukherjee at 10). I disagree because this definition of ordinary skill is too broad. It encompasses persons who do not have any relevant technical degrees and relevant experience. For example, Dr. Mukherjee's definition includes someone with no education that is relevant to suture design and no suture design experience.

Dr. Mukherjee takes the UHMW PE from the core of the *hollow braid* of Figs. 8 and 9 and matches it with either the (1) bioabsorbable polyester of the *sternum closure device* or (2) the material of the *spiroid braid* of Fig. 7. This picking and choosing of two different materials from two different structures does not teach a single suture construction having the claimed first and second fiber forming materials braided in direct intertwining contact as claimed in the 446 Patent.

78. Dr. Mukherjee also cites to column 7, lines 59-60, as disclosing a heterogeneous braid with direct intertwining contact where one of the yarns is PE (Mukherjee at 14-16). But column 7, lines 59-60 of Chesterfield only describes PE in the core. The PE referred to in column 7, lines 59-60, is not in the sheath, is not described as braided with another material, is not described as braided with the claimed second fiber-forming materials (nylon, aramid, or PET), and is not described as braided in direct intertwining contact with the claimed second fiber-forming materials.

79. Dr. Mukherjee also cites to claims 11 and 12 of the 575 patent as disclosing nylon and polyester respectively braided in direct intertwining contact with UHMW PE in a heterogeneous suture braid as claimed in the 446 patent. I disagree. Claims 11 and 12 of the 575 patent refer to second non-absorbable fibers as being formed from either nylon or polyester. But claims 11 and 12 of Chesterfield do not specify how the second fibers are braided with the claimed first fibers. For example, Chesterfield claims 11 and 12 do not recite that the first and second fibers are braided in direct intertwining contact, as opposed to a core-sheath arrangement (like that described in Chesterfield Figs. 8, reproduced below, & 9), with the first fiber materials only in the core and the second fiber materials only in the sheath.



80. Further, claims 11 and 12 recite a “method for repairing split portions of body tissue comprising looping a flexible elongated member about the body tissue...” (Ex. 6 at 8:29-38; 60-65). It is my opinion that this refers to a method of using the sternum closure device, not a suture, because a sternum closure goes “about” the margins of tissue (Ex. 6 at Fig. 1) while a suture goes through tissue. Thus, claims 11 and 12 do not refer to a suture and therefore cannot teach all the limitations of the claims of the 446 Patent.

81. Dr. Mukherjee also cites to Chesterfield at column 4, lines 9-23, as disclosing the second fiber forming materials (PET, nylon, or aramid) braided in direct intertwining contact with the first-fiber forming materials (Mukherjee at 16). But that portion of Chesterfield does not explicitly mention nylon, aramid, or PET. Although, that citation does state that “[a]ny number of combinations of bioabsorbable yarns, filamentary or otherwise, and/or non-absorbable, and high strength filaments are contemplated” (Ex. 6 at 4:20-24), it does not disclose how these materials are selected or arranged, such that a person of ordinary skill in the art would understand that nylon, aramid, or PET are necessarily disclosed and arranged as claimed in the 446 patent. For example, it does not disclose PET, Nylon, or aramid braided in direct intertwining contact with UHMW PE, as claimed in the 446 Patent.

EXHIBIT 44

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.,)	
a Private Limited Company)	
of the United Kingdom,)	
)	
Defendants.)	

Rebuttal Expert Report of Dr. David Brookstein

I. Background Information

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

II. Summary of Opinions

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.

Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

15. My opinion is supported by Mr. Grafton's testimony regarding the development of FiberWire and by Arthrex's 234 patent. As Mr. Grafton explained, he had developed a suture having a homogeneous braid of UHMWPE (Ex. I at 51:15-17). But he found this UHMWPE braid to be unacceptable because it had poor knot holding strength properties (Ex. I at 45:16-46:15; 50:1-53:7). As Mr. Grafton explained, the poor knot holding strength properties were attributable to UHMWPE being a lubricous material, which causes the knot to slip (Ex. I at 52:24-53:7). To increase the knot holding strength, Mr. Grafton braided UHMWPE with PET (Ex. I at 53:20-54:5; 46:16-47:5). Mr. Grafton tested the UHMWPE and PET braid and found that it had improved knot holding strength properties as compared to the UHMWPE braid (*i.e.*, the heterogeneous braid did not slip like the homogeneous UHMWPE braid) (Ex. I at 54:24-55:1). This type of UHMWPE and PET braid ultimately became FiberWire. Thus, as Mr. Grafton's experience shows, FiberWire is a braid of UHMWPE (a lubricous yarn) with PET, and the PET increases the knot holding strength of the braid. Accordingly, FiberWire's braid is not, as Dr. Mukherjee opines, the opposite of what is described in the 446 Patent.

16. Arthrex's 234 Patent also supports my opinion. According to Mr. Grafton's 234 Patent, UHMWPE, "while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications" (Ex. R at 1:19-21; Ex. I at 104:9-15). Mr. Grafton defines knot tie down as a strength, namely the "ability to approximate the tissue and hold [tissue] in place through biomechanical forces" in the body (Ex. I at 26:24-27:2). Mr. Grafton's definition of knot tie down is part of what I refer to as knot holding strength.

A. If the Novel And Basic Characteristics Have The Definitions Provided By Dr. Mukherjee, FiberWire's Coating Does Not Materially Affect Them

23. According to Dr. Mukherjee, the novel and basic characteristics are “a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties” (Mukherjee Res. Report at 18). Dr. Mukherjee opines that FiberWire's coating materially affects this novel and basic characteristic. I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a “material” affect on the basic and novel characteristics; and (iii) Dr. Mukherjee's tests are flawed or inconclusive. I describe each of these three points below.

1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

24. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface “lubricant” (Mukherjee Res. Report at Ex. 16).

materials to optimize all these properties in the product?

A. Yes.

(Ex. I at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?

A. All materials used.

(Ex. T at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

27. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasurable (Ex. U at 119:5-9; Ex. V at 94:2-9; Ex. W at 48:1-50:16; Ex. X at ARM2104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed³ and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters

³ Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

per minute (Ex. U at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. U at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. U at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. U at 95:14-17). The process is then repeated. I have measured the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DM Exhibits 284, 342, and 285). I determined that the linear density of Ex. 284 (uncoated) is 2393 denier, Ex. 342 (coated once) is 2474 denier, and Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from Ex. 342. Thus, the total pick-up of Ex. 285 over Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Mukherjee Res. Report at Ex. 16).

coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

31. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Dr. Mukherjee, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Dr. Mukherjee.

32. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. D at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (Ex. D at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

33. I disagree with Dr. Mukherjee's opinion that FiberWire's coating has a "material" effect because he basically *excludes* coated sutures from the 446 Patent claims (Mukherjee Res. Report at 22). But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to *further* improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. *Most preferably*, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating *may be* eliminated saving expense as well as avoiding the associated braid stiffening.

(Ex. D at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them, as Dr. Mukherjee opines. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

34. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Dr. Mukherjee attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set of continuous and discrete yarns (Ex. D at 2:40-41). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (Ex. D at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (Ex. D at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. V at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. D at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. E-G attached to my first report and CETR's images. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as

EXHIBIT 45

United States Patent [19][11] **Patent Number:** **5,019,093****Kaplan et al.**[45] **Date of Patent:** **May 28, 1991**[54] **BRAIDED SUTURE**[75] **Inventors:** **Donald S. Kaplan, Weston; Matthew E. Hermes, Easton, both of Conn.**[73] **Assignee:** **United States Surgical Corporation, Norwalk, Conn.**[21] **Appl. No.:** **491,215**[22] **Filed:** **Mar. 9, 1990****Related U.S. Application Data**

[63] Continuation of Ser. No. 344,745, Apr. 28, 1989, which is a continuation-in-part of Ser. No. 227,699, Aug. 3, 1988, abandoned, which is a continuation-in-part of Ser. No. 89,732, Aug. 26, 1987, abandoned.

[51] **Int. Cl.⁵** **A61B 17/06**[52] **U.S. Cl.** **606/228; 606/230**[58] **Field of Search** **606/228, 229, 230, 231; 139/387, 388; 87/6, 8, 9**[56] **References Cited****U.S. PATENT DOCUMENTS**

3,125,095	3/1964	Kaufman et al.	128/335.5
3,187,752	6/1965	Glick	128/335.5
3,297,033	1/1967	Schmitt	128/335.5
3,359,983	12/1967	Northey	128/335.5
3,371,069	2/1968	Miyamae et al.	128/335.5
3,565,077	2/1971	Glick	128/335.5

3,772,420	11/1973	Glick et al.	128/335.5
3,949,755	4/1976	Vauquios	128/335.5
3,949,756	4/1976	Aee	128/339
4,014,973	3/1977	Thompson	128/335.5
4,024,871	5/1977	Stephenson	128/335.5
4,043,344	8/1977	Landi et al.	606/230
4,047,533	9/1977	Perciaccante et al.	606/230
4,201,216	5/1980	Mattei	128/335.5
4,204,542	5/1980	Bokros et al.	128/335.5
4,321,038	3/1982	Porteous	128/335.5
4,362,162	12/1982	Nakajima et al.	128/334 R
4,546,769	10/1985	Planck et al.	606/231
4,621,638	11/1986	Silvestrini	128/335.5
4,792,336	12/1988	Hlavacek et al.	128/335.5

Primary Examiner—Randall L. Green**Assistant Examiner**—Gary Jackson**Attorney, Agent, or Firm**—Thomas R. Bremer; Peter G. Dilworth; Rocco S. Barrese[57] **ABSTRACT**

A braided suture is provided which exhibits perceptibly enhanced flexibility and hand as well as reduced chatter and drag compared to these same characteristics in a suture possessing substantially the same overall denier but possessing significantly fewer sheath yarns and denier of individual filaments than the braided suture herein.

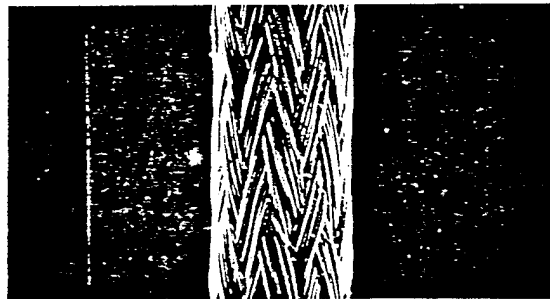
48 Claims, 5 Drawing Sheets

FIG. 1

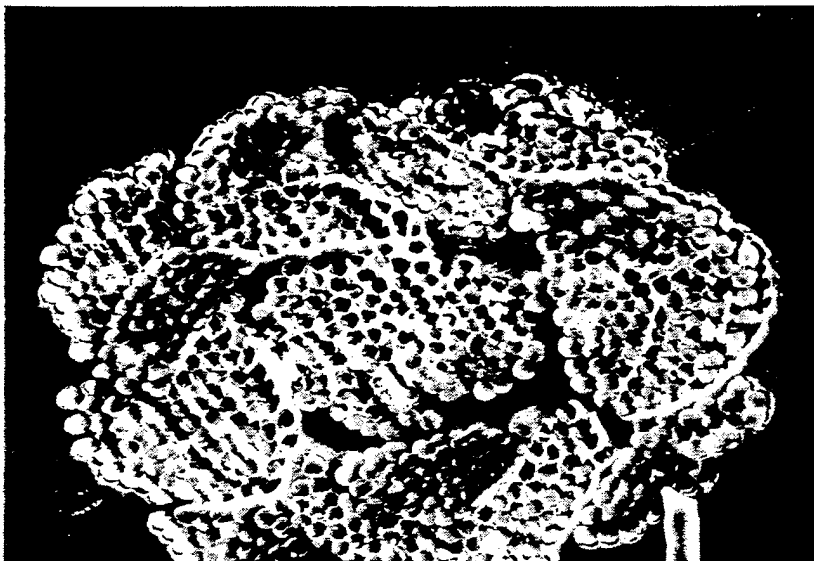


FIG. 2

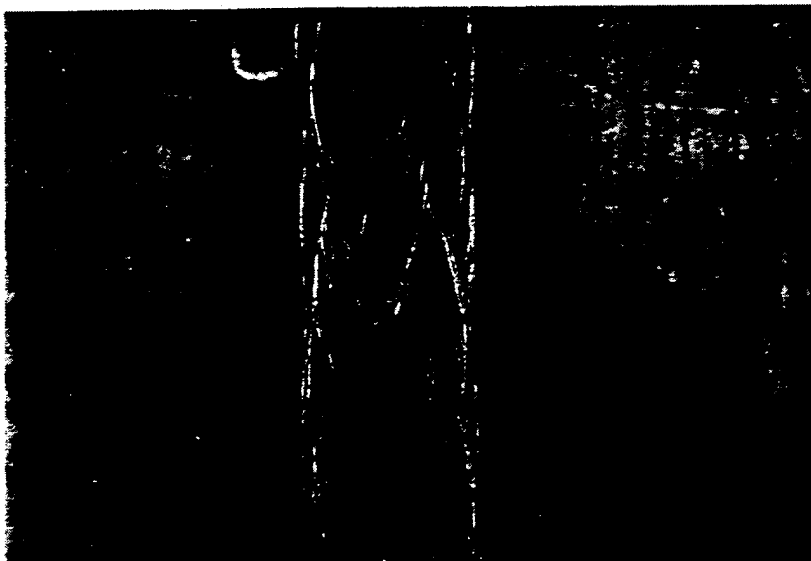


FIG.3

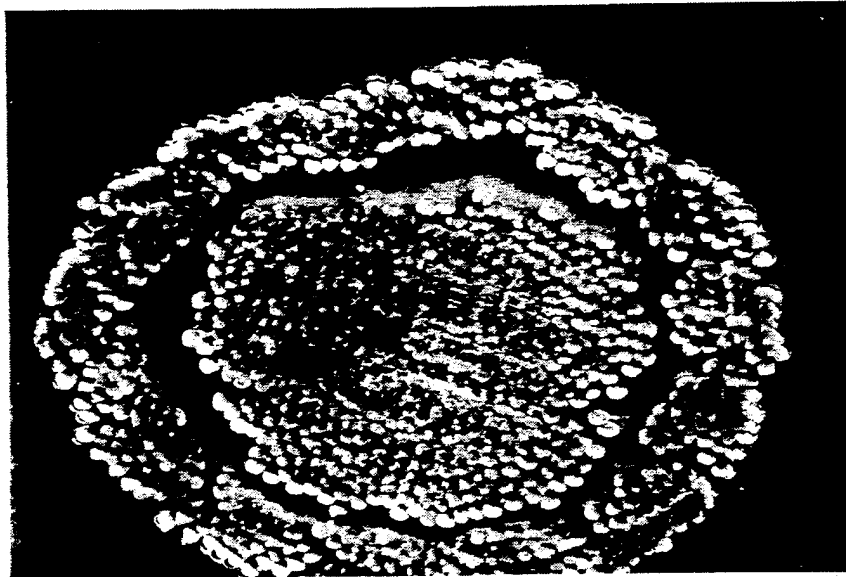


FIG.4

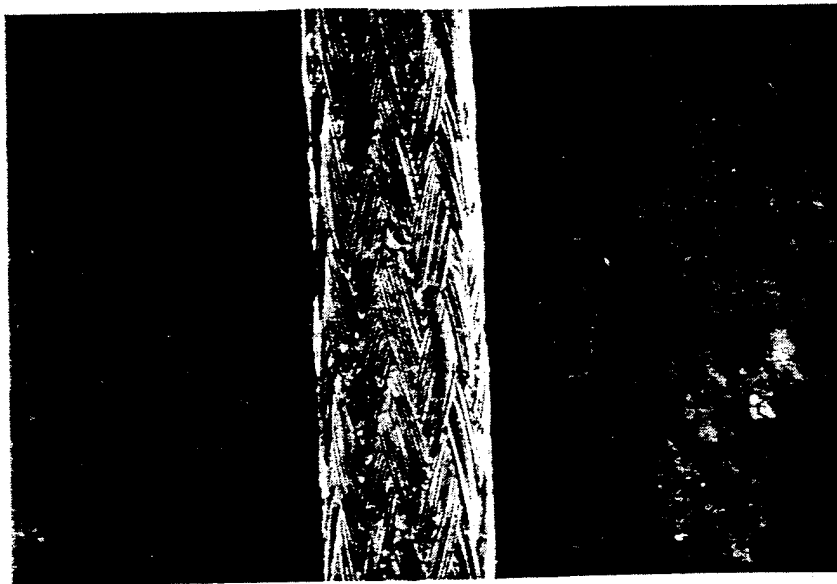


FIG. 5

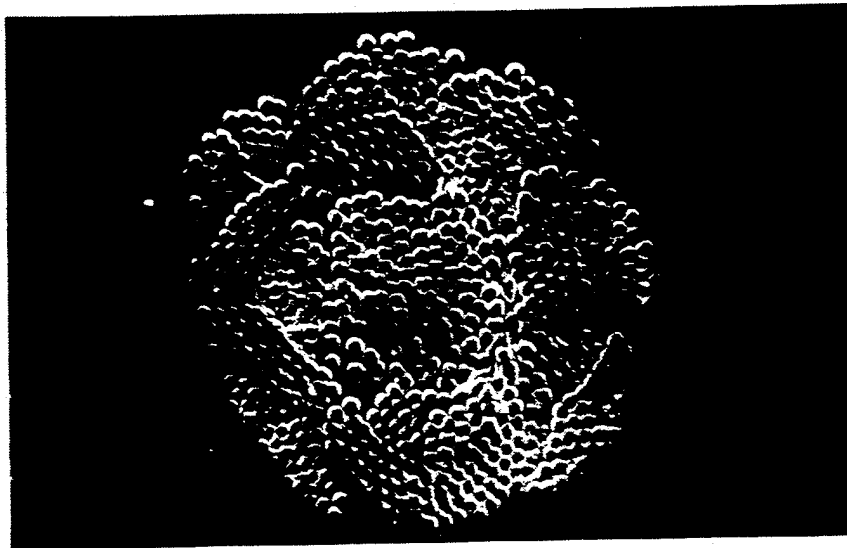


FIG. 6



FIG. 7

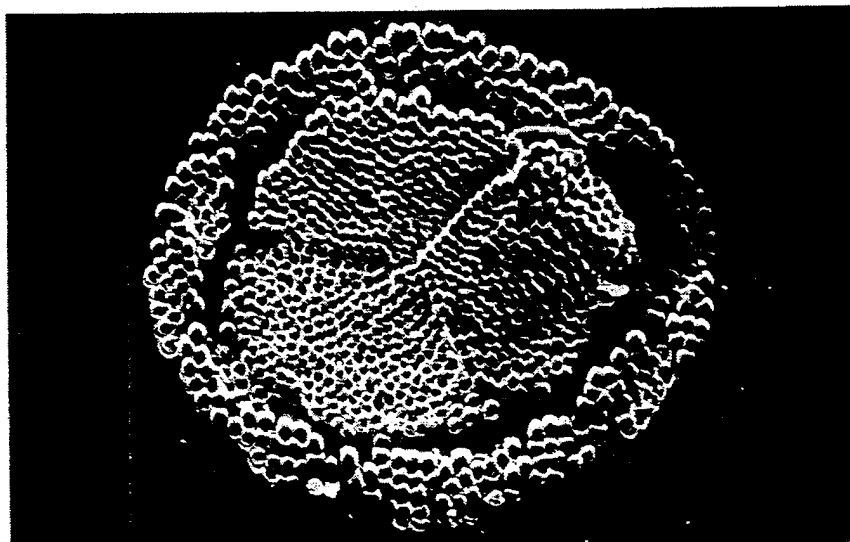


FIG. 8



FIG.9

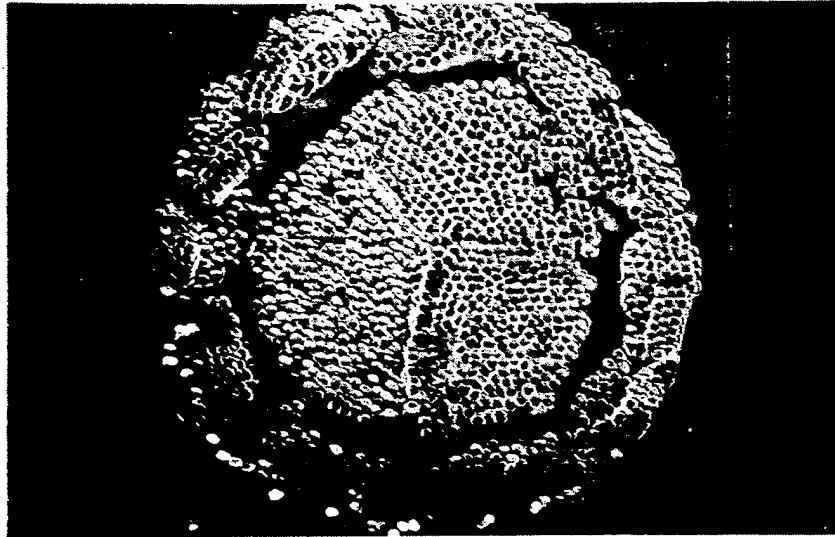


FIG.10



5,019,093

1

BRAIDED SUTURE**CROSS REFERENCE TO RELATED APPLICATION**

This application is a continuation of commonly assigned, copending U.S. Pat. application Ser. No. 344,745, filed Apr. 28, 1989 as a continuation-in-part of commonly assigned, U.S. Pat. application Ser. No. 227,699, filed Aug. 3, 1988 now abandoned, as a continuation-in-part of commonly assigned, U.S. Pat. application Ser. No. 89,732, filed Aug. 26, 1987, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to a braided suture of improved construction.

Sutures intended for the repair of body tissues must meet certain requirements: they must be substantially non-toxic, capable of being readily sterilized, they must have good tensile strength and have acceptable knot-tying and knot-holding characteristics and if the sutures are of the absorbable or biodegradable variety, the absorption or biodegradation of the suture must be closely controlled.

Sutures have been constructed from a wide variety of materials including surgical gut, silk, cotton, a polyolefin such as polypropylene, polyamide, polyglycolic acid, polyesters such as polyethylene terephthalate and glycolide-lactide copolymer, etc. Although the optimum structure of a suture is that of a monofilament, since certain materials of construction would provide a stiff monofilament suture lacking acceptable knot-tying and knot-holding properties, sutures manufactured from such materials are preferably provided as braided structures. Thus, for example, sutures manufactured from silk, polyamide, polyester and bio-absorbable glycolide-lactide copolymer are usually provided as multifilament braids. Commercial examples of such sutures include DEXON (Davis & Geck, Inc.,) and VICRYL (Ethicon, Inc.).

Currently available braided suture products are acceptable in terms of their knot-tying and knot-holding properties. However, as removed from the package, they tend to be stiff and wiry and retain a "set" or "memory" such that at the time of use, it is usually necessary for the surgeon or assistant personnel to flex and stretch the suture to make it more readily handleable. Furthermore, the surfaces of known sutures are perceptibly rough. Thus, if one passes one's hand or fingers along the braid, surface irregularities will be readily detected. The result of this rough surface is that the suture will exhibit drag or chatter as it is drawn through tissue, characteristics which militate against smooth, neat, accurately placed wound approximation so necessary to excellence in surgical practice.

In the case of one braided suture now on the market, due to the necessity of having to meet fiber strength requirements while at the same time retaining acceptable knot-tying and knot-holding properties, the suture is constructed from a greater amount of fiber and consequently is of larger diameter than the accepted industry standard.

It is an object of this invention to provide a braided suture of improved characteristics, specifically one exhibiting greater flexibility, better hand and less chatter and drag, than braided sutures of known construction.

2

It is a particular object of the invention to provide a braided suture possessing a greater number of sheath yarns, a finer denier for the individual filaments comprising an individual sheath yarn and a greater pick count for a suture of any given overall denier (cross-overs per linear inch).

It is still another object of the invention to provide a braided absorbable suture possessing the aforesaid improved characteristics.

SUMMARY OF THE INVENTION

By way of satisfying the foregoing objects as well as other objects of the invention, there is provided in accordance with this invention a braided suture of improved construction possessing a significantly greater number of sheath yarns for a given overall denier, said sheath yarns being fabricated from individual filaments of finer denier than filaments which are typical of known types of braided suture, said improved suture exhibiting perceptibly improved flexibility and hand and reduced chatter and drag compared with braided sutures of known construction.

More particularly, in accordance with this invention, a braided suture of improved construction is provided wherein for a given range of overall suture denier, the range of pick count, number of sheath yarns and denier of individual filaments comprising a sheath yarn are related to each other as follows:

Overall Suture Denier	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments
from about 50 to about 125	from about 50 to about 100	from about 4 to about 16	from about 0.2 to about 1.8
greater than about 125 to about 200	from about 50 to about 100	from about 4 to about 16	from about 0.2 to about 1.8
greater than about 200 to about 300	from about 50 to about 100	from about 4 to about 16	from about 0.2 to about 1.8
greater than about 300 to about 500	from about 50 to about 100	from about 10 to about 20	from about 0.2 to about 6.0
greater than about 500 to about 800	from about 50 to about 100	from about 14 to about 20	from about 0.2 to about 6.0
greater than about 800 to about 1200	from about 50 to about 100	from about 16 to about 32	from about 0.2 to about 6.0
greater than about 1200 to about 2000	from about 50 to about 100	from about 20 to about 36	from about 0.2 to about 6.0
greater than about 2000 to about 4000	from about 50 to about 100	from about 20 to about 36	from about 0.2 to about 6.0

As a result of its possessing a greater pick count and/or a greater number of sheath yarns for a suture of given overall denier and in some cases, a finer denier for the individual filaments making up a sheath yarn, the braided suture of the present invention exhibits far fewer surface discontinuities thereby providing a suture which is considerably smoother than braided sutures of known construction.

The term "suture" is intended to embrace both the non-absorbable as well as the bio-absorbable varieties.

The term "braid" or "braided" as applied to the suture of this invention refers to an arrangement of discrete units, or bundles, denominated "sheath yarns", made up of individual filaments with individual sheath

5,019,093

3

yarns interlocking or interlacing each other in a regular criss-cross pattern.

The term "pick count" refers to the number of cross-overs of sheath yarns per linear inch of suture and, together with the overall denier of the suture, the denier of the individual filaments constituting a sheath yarn and the number of sheath yarns employed, defines the principal construction characteristics of the braided suture herein.

The braided suture of this invention can optionally possess, in addition to the braided structure itself, a core component around which the braid is constructed. In the case of this embodiment, it is preferred that the core constitute a larger proportion of overall suture denier than the core component of a known braided suture

BRIEF DESCRIPTION OF THE ACCOMPANYING FIGURES

The accompanying figures are photomicrographs of cross-sectional and linear views of braided sutures both within (FIGS. 3, 4 and 7 to 10) and outside (FIGS. 1, 2, 5 and 6) the scope of this invention, the latter being presented for comparison purposes.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In a preferred embodiment, the braided suture of the present invention is fabricated from a bio-absorbable or biodegradable resin such as one derived from polyglycolic acid, glycolide, lactic acid, lactide, dioxanone, trimethylene carbonate, etc., and various combinations of these and related monomers. Sutures prepared from resins of this type are known in the art, e.g., as disclosed in U.S. Pat. Nos. 2,668,162; 2,703,316; 2,758,987; 3,225,766; 3,297,033; 3,422,181; 3,531,561; 3,565,077; 3,565,869; 3,620,218; 3,626,948; 3,636,956; 3,736,646; 3,772,420; 3,773,919; 3,792,010; 3,797,499; 3,839,297; 3,867,190; 3,878,284; 3,982,543; 4,047,533; 4,060,089; 4,137,921; 4,157,437; 4,234,775; 4,237,920; 4,300,565; and, 4,523,591; U.K. Patent No. 779,291; D. K. Gilding et al., "Biodegradable polymers for use in surgery—polyglycolic/poly(lactic acid) homo- and copolymers: 1, Polymer, Volume 20, pages 1459-1464 (1979), and D. F. Williams (ed.), Biocompatibility of Clinical Implant Materials, Vol. II, ch. 9: "Biodegradable Polymers" (1981).

The defining characteristics of the braided suture of this invention, apart from the material of its construction, are:

- (1) overall suture denier;
- (2) the pattern of the interlocking yarns expressed as the pick count, which is to say, the number of crossovers of individual sheath yarns per linear inch of suture;
- (3) the number of sheath yarns comprising the braid;
- (4) the denier of the individual filaments comprising each sheath yarn; and,
- (5) the denier of the core, where present.

(1) Overall Denier of the Suture

The overall denier of the braided suture can vary from about 50 to about 4000. Within this range, the ranges of overall denier for particular sutures are: from about 50 to about 125 denier; from above about 125 to about 200 denier; from above about 200 to about 300 denier; from above about 300 to about 500 denier; from above about 500 to about 800 denier; from above about 800 to about 1500 denier; from above about 1500 to

4

about 2000 denier; and, from above about 2000 to about 3600 denier.

(2) Pattern of the Interlocking Sheath Yarns (Pick Count)

For a suture of any range of overall denier, pick count can vary from about 50 to about 100 crossovers/inch with about 55-80 crossovers/inch being preferred. For sutures constructed within any range of overall denier, as larger numbers of sheath yarns are employed, the pick-count for acceptable sutures will also increase within the above ranges.

For a suture of a particular range of denier and number of sheath yarns, pick count is advantageously established to achieve a balance in the properties desired. In general, with increasing pick count, surface roughness of the suture tends to increase and with decreasing pick count, the ability of the external braided sheath to contain the core (if present) tends to decrease even reaching the point where the braid may become so loose as to result in the core protruding therethrough.

For sutures of any specific denier range and number of sheath yarns, it is preferable to have as low a pick count as possible in order to achieve optimum surface smoothness, consistent, of course, with the need to provide a compact braid which prevents the core (if present) from protruding through the exterior sheath yarn structure.

(3) The Number of Sheath Yarns

The number of sheath yarns bears some relation to overall suture denier, the number generally increasing with the weight of the suture. Thus, across the range of suture weight (denier) indicated above, the braided suture of this invention can be constructed with from about 4 up to as many as about 36 individual sheath yarns constructed from individual filaments having the deniers discussed below.

Table I below sets forth broad and preferred ranges for the numbers of sheath yarns which are suitable for the construction of braided sutures of various ranges of overall denier. The pick counts of the sutures vary from about 50 to about 100 and deniers of individual filaments vary from about 0.2 to about 6.0 for the broad range of number of sheath yarns and the pick counts vary from about 55 to about 80 and the deniers of individual filaments vary from about 0.8 to about 3.0, and advantageously from about 0.8 to about 1.4, for the preferred range of number of sheath yarns.

TABLE I

Sheath Yarns Related to Suture Denier			
Overall Suture Denier	Suture Size	Number of Sheath Yarns (Broad Range)	Number of Sheath Yarns (Preferred Range)
50 to about 125	7/0,8/0	4-16	6-14
greater than about 125 to about 200	6/0	4-16	6-14
greater than about 200 to about 300	5/0	4-16	6-14
greater than about 300 to about 500	4/0	10-20	12-14
greater than about 500 to about 800	3/0	14-20	14-18
greater than about 800 to about 1200	2/0	18-32	20-30
greater than about 1200 to about 2000	0	20-36	24-34
greater than about 2000 to about 4000	1,2	20-36	24-34

5,019,093

5

While the sheath yarns need not be twisted, it is generally preferred that they be provided with a twist so as to minimize snagging during braid construction.

(4) Individual Filament Denier

The individual filaments comprising each sheath yarn can vary in weight from about 0.2 to about 6.0 denier, preferably from about 0.8 to about 3.0 denier and more preferably from about 0.8 to about 1.4 denier. The number of such filaments present in a particular sheath yarn will depend on the overall denier of the suture as well as the number of sheath yarns utilized in the construction of the suture. Table II sets forth some typical numbers of filaments per sheath yarn for both the broad and preferred ranges of filament weight:

TABLE II

Number of Filaments per Sheath Yarn		
approximate minimum	approximate maximum	Filament Denier
45	450	0.2
15	150	0.5
5	50	1.5
3	40	1.8
1	15	6.0

(5) Core (Optional)

For all but the lowest range of overall denier, the braided suture herein can optionally be constructed around a filamentous core which itself can be braided or which can be provided in some other configuration such as a twist, ply, cable, etc. The filament(s) comprising the core need not be as fine as those comprising the sheath yarns. It is particularly advantageous for sutures of heavier denier to possess a core. Where a core is provided, it is generally preferred that it possess a weight which is significantly greater than that of a core of a known suture of equivalent overall denier.

Table III below provides some typical core deniers for sutures of various deniers.

TABLE III

Core Denier Related to Suture Denier			
Overall Suture Denier	Suture Size	Denier of Optional Core (Broad Range)	Denier of Optional Core (Preferred Range)
from about 50 to about 125	8/0,7/0	none	none
greater than about 125 to about 200	6/0	20-80	25-50
greater than about 200 to about 300	5/0	30-100	50-80
greater than about 300 to about 500	4/0	80-50	80-120
greater than about 500 to about 800	3/0	150-300	180-280
greater than about 800 to about 1200	2/0	250-700	350-650
greater than about 1200 to about 2000	0	400-1200	500-1000
greater than about 2000 to about 4000	1,2	800-2400	1000-2200

It can be advantageous to apply one or more coating compositions to the braided suture of this invention to

6

improve such properties as surface lubricity and knot tiedown behavior. A variety of suture coating compositions proposed for either or both purposes is known in the art, e.g., those disclosed in U.S. Pat. No. 4,047,533, the contents of which are incorporated by reference herein.

It is also within the scope of this invention to impregnate the suture with, or otherwise apply thereto, one or more medico-surgically useful substances, e.g.; those which accelerate or beneficially modify the healing process when the suture is applied to a wound or surgical site. So, for example, the braided suture herein can be provided with a therapeutic agent which will be deposited at the sutured site. The therapeutic agent can be chosen for its antimicrobial properties, capability for promoting wound repair and/or tissue growth or for specific indications such as thrombosis. Antimicrobial agents such as broad spectrum antibiotics (gentamycin sulphate, erythromycin or derivatized glycopeptides) which are slowly released into the tissue can be applied in this manner to aid in combating clinical and sub-clinical infections in a surgical or trauma wound site. To promote wound repair and/or tissue growth, one or several growth promoting factors can be introduced into the suture, e.g., fibroblast growth factor, bone growth factor, epidermal growth factor, platelet derived growth factor, macrophage derived growth factor, alveolar derived growth factor, monocyte derived growth factor, magainin, and so forth. Some therapeutic indications are: glycerol with tissue or kidney plasminogen activator to cause thrombosis, superoxide dismutase to scavenge tissue damaging free radicals, tumor necrosis factor for cancer therapy or colony stimulating factor and interferon, interleukin-2 or other lymphokine to enhance the immune system.

In the examples which follow, Comparison Examples 1 to 11 are illustrative of known type sutures while Examples 1 to 12 are illustrative of sutures constructed in accordance with this invention.

COMPARISON EXAMPLES 1-7

The following braided suture configurations are disclosed in U.S. Pat. No. 3,565,077;

Comparison Example	Overall Suture Denier	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments	Denier of Core
1	175	40	6	6	25
2	300	46	8	6	100
3	500	40	8	6	100
4	800	50	12	6	200
5	1200	50	16	6	400
6	1500	50	12	6	600
7	2000	40	16	6	800

Sutures possessing approximately these configurations are relatively inflexible, rough-surfaced and exhibit a relatively high level of chatter and drag.

COMPARISON EXAMPLES 8-11

The following braided suture configurations are those of four commercially available sutures:

Comparison Example	Overall Suture Denier	Suture Size	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments	Denier of Core
8	259	5/0	47	8	2.1	29

5,019,093

7

8

-continued

Comparison Example	Overall Suture Denier	Suture Size	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments	Denier of Core
9	698	3/0	52	12	2.1	55
10	1566	0	50	16	2.1	252
11	2122	1	44	16	2.2	330

Photomicrographs obtained by scanning electron microscopy (SEM) of the suture of Comparison Example 10 (FIGS. 1 and 2: cross-sectional view at 200 \times and linear view at 50 \times , respectively) clearly show the structural details of the suture. The suture braid is made up of relatively few sheath yarns and the circumferen-

drag compared with the known sutures of Comparison Examples 1-11.

EXAMPLES 9-12

The following braided sutures were fabricated in accordance with the present invention:

Example	Overall Suture Denier	Suture Size	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments	Denier of Core
9	240	5/0	68	8	1.2	40
10	600	3/0	71	16	1.2	180
11	1374	0	67	28	1.2	702
12	2230	1	57	32	1.2	975

tial indentations, plainly evident in FIG. 1, cause the braid surface to be relatively rough.

EXAMPLES 1-8

These examples illustrate various size braided sutures constructed in accordance with the present invention.

Example	Overall Suture Denier	Suture Size	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments	Denier of Core
1	96	7/0	82	8	1.2	—
2	173	6/0	75	12	1.2	29
3	240	5/0	65	8	1.2	48
4	389	4/0	75	12	1.2	101
5	600	3/0	65	16	1.2	216
6	1080	2/0	72	24	1.2	504
7	1378	0	65	28	1.2	706
8	2028	1	65	32	1.2	1260

Comparing the details of construction of the foregoing braided sutures with those of the known braided sutures as set forth in Comparison Examples 1-11, it will be noted that for sutures of comparable overall denier, the suture of this invention possesses a significantly greater pick count and number of sheath yarns and a significantly finer denier for the individual filaments making up a sheath yarn than the equivalent characteristics of the known

As a result of their unique construction characteristics, the sutures of this invention exhibit perceptibly improved flexibility and hand and reduced chatter and

In contrast to the suture of Comparison Example 10, supra, SEM photomicrographs of the suture of Example 11 (FIGS. 3 and 4: cross-sectional view at 200 \times and linear view at 50 \times , respectively) show a smooth circumferential surface as the result of the increased number of sheath yarns and smaller diameter of individual

filaments.

FIG. 1 as compared to FIG. 3 shows the relatively larger core present in the suture of Example 11 as compared to that of Comparison Example 10.

Comparison between FIGS. 2 and 4 shows the increased number of picks (crossovers/inch) of the suture of Example 11 as compared to that of Comparison Example 10.

EXAMPLES 13-15

The following suture braids were fabricated in accordance with the present invention:

Example	Overall Suture Denier	Suture Size	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments	Denier of Core
13	1442	0	70	28	2.0*	882
14	1621	0	70	28	1.2	882
15	1554	0	78	28	1.2	882

*Denier of sheath filaments; core filaments were 1.2 dpf.

5,019,093

9

The suture braids were coated to improve suture lubricity and knot tie-down characteristics and compared for physical properties for diameter USP knot-pull and suture tissue drag with the coated commercial suture of Comparison Example 10.

In this tissue drag test, sutures were needled with identical tapered needles to normalize any effect of needle diameter on the test.

Sutures were passed through live animal abdominal fascia tissue. The results of the tissue drag study are shown in Table IV as follows:

TABLE IV

Example	Tissue Drag Results		
	Diameter (mm)	Knot-Pull (Kg)	Tissue Drag (gms force, maximum)
Comparison Example 10	0.419	4.72	257
13	0.413	5.27	35
14	0.428	5.35	56
15	0.444	5.04	50

These data clearly show that the smoother surface of the braided sutures fabricated in accordance with this invention provide smoother, more resistance-free passage of the suture through tissue thereby resulting in lower tissue drag and chatter. High drag forces make it more difficult for the surgeon to align tissue neatly and increase the time to complete the closure. A visual comparison of the suture of Comparative Example 10 and those of Examples 13 and 14 of this invention are consistent with the tissue drag observations set forth above. Thus, it is evident from a visual comparison of the SEM photomicrographs of FIGS. 5 and 6 (suture of Comparison Example 10 shown in cross-sectional view at 150 \times and linear view at 70 \times , respectively) with those of FIGS. 7 and 8 (suture of Example 13 shown in cross-section at 150 \times and linear view at 70 \times , respectively) and FIGS. 9 and 10 (suture of Example 14 shown in cross-section at 150 \times and linear view at 70 \times , respectively) that the external surfaces of the sutures of the present invention, i.e., those of Examples 13 and 14, are perceptibly smoother than the surfaces of the suture of Comparison Example 10.

What is claimed is:

1. A braided suture of improved construction wherein for a given range of overall suture denier, the range of pick count, number of sheath yarns and denier of individual filaments comprising a sheath yarn are related to each other as follows:

Overall Suture Denier	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments
from about 50 to about 125	from about 50 to about 100	from about 4 to about 16	from about 0.2 to about 1.8
greater than about 125 to about 200	from about 50 to about 100	from about 4 to about 16	from about 0.2 to about 1.8
greater than about 200 to about 300	from about 50 to about 100	from about 4 to about 16	from about 0.2 to about 1.8
greater than about 300 to about 500	from about 50 to about 100	from about 10 to about 20	from about 0.2 to about 1.8
greater than about 500 to about 800	from about 50 to about 100	from about 14 to about 20	from about 0.2 to about 1.8
greater than about 800 to about 1200	from about 50 to about 100	from about 16 to about 32	from about 0.2 to about 1.8

10

-continued

Overall Suture Denier	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments
greater than about 1200 to about 2000	from about 50 to about 100	from about 20 to about 36	from about 0.2 to about 1.8
greater than about 2000 to about 4000.	from about 50 to about 100	from about 20 to about 36	from about 0.2 to about 1.8

2. The braided suture of claim 1 wherein for a given overall suture denier, the range of pick count, number of sheath yarns and denier of individual filaments comprising a sheath yarn are related to each other as follows:

Overall Suture Denier	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments
from about 50 to about 125	from about 55 to about 80	from about 6 to about 14	from about 0.8 to about 1.4
greater than about 125 to about 200	from about 55 to about 80	from about 6 to about 14	from about 0.8 to about 1.4
greater than about 200 to about 300	from about 55 to about 80	from about 6 to about 14	from about 0.8 to about 1.4
greater than about 300 to about 500	from about 55 to about 80	from about 12 to about 14	from about 0.8 to about 1.4
greater than about 500 to about 800	from about 55 to about 80	from about 14 to about 18	from about 0.8 to about 1.4
greater than about 800 to about 1200	from about 55 to about 80	from about 20 to about 30	from about 0.8 to about 1.4
greater than about 1200 to about 2000	from about 55 to about 80	from about 24 to about 34	from about 0.8 to about 1.4
greater than about 2000 to about 4000.	from about 55 to about 80	from about 24 to about 34	from about 0.8 to about 1.4

3. The braided suture of claim 2 possessing a core.

4. The braided suture of claim 3 wherein the individual filaments are fabricated from a bio-absorbable polymer.

5. The braided suture of claim 4 wherein the individual filaments are fabricated in whole or in part from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

6. The braided suture of claim 2 wherein the individual filaments are fabricated from a bio-absorbable polymer.

7. The braided suture of claim 6 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

8. The braided suture of claim 1 possessing a core.

9. The braided suture of claim 8 wherein the overall suture denier and core denier are related to each other as follows:

Overall Suture Denier	Denier of Core
greater than about 125 to about 200	from about 20 to about 80
greater than about 200 to about 300	from about 30 to about 100

11

-continued

Overall Suture Denier	Denier of Core
greater than about 300 to about 500	from about 80 to about 150
greater than about 500 to about 800	from about 150 to about 300
greater than about 800 to about 1200	from about 250 to about 700
greater than about 1200 to about 2000	from about 400 to about 1200
greater than about 2000 to about 4000.	from about 800 to about 2400

10. The braided suture of claim 9 wherein the overall suture denier and core denier are related to each other as follows:

Overall Suture Denier	Denier of Core
greater than about 125 to about 200	from about 25 to about 50
greater than about 200 to about 300	from about 50 to about 80
greater than about 300 to about 500	from about 80 to about 120
greater than about 500 to about 800	from about 180 to about 280
greater than about 800 to about 1200	from about 350 to about 650
greater than about 1200 to about 2000	from about 500 to about 1000
greater than about 2000 to about 4000.	from about 1000 to about 2200

11. The braided suture of claim 10 wherein the individual filaments are fabricated from a bio-absorbable polymer.

12. The braided suture of claim 11 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

13. The braided suture of claim 9 wherein the individual filaments are fabricated from a bio-absorbable polymer.

14. The braided suture of claim 13 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

15. The braided suture of claim 8 wherein the individual filaments are fabricated from a bio-absorbable polymer.

16. The braided suture of claim 15 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

17. The braided suture of claim 1 wherein the individual filaments are fabricated from a non-absorbable material.

18. The braided suture of claim 17 wherein the non-absorbable material is cotton, silk, polyamide or polyolefin.

19. The braided suture of claim 1 wherein the individual filaments are fabricated from a bio-absorbable polymer.

20. The braided suture of claim 19 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected

12

from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

21. The braided suture of claim 1 surface coated with a composition enhancing one or more functional properties of the suture.

22. The braided suture of claim 1 containing at least one medico-surgically useful substance.

23. The braided suture of claim 1 containing at least one growth factor.

24. The braided suture of claim 1 containing at least one growth factor selected from the group consisting of fibroblast growth factor, bone growth factor, epidermal growth factor, platelet derived growth factor, macrophage derived growth factor, alveolar derived growth factor, monocyte derived growth factor and magainin.

25. A braided suture of improved construction wherein for a given range of overall suture denier, the range of pick count, number of sheath yarns and denier of individual filaments comprising a sheath yarn are related to each other as follows:

Overall Suture Denier	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments
greater than about 300 to about 500	from about 50 to about 100	from about 10 to about 20	from about 0.2 to about 6.0
greater than about 500 to about 800	from about 50 to about 100	from about 14 to about 20	from about 0.2 to about 6.0
greater than about 800 to about 1200	from about 50 to about 100	from about 16 to about 32	from about 0.2 to about 6.0
greater than about 1200 to about 2000	from about 50 to about 100	from about 20 to about 36	from about 0.2 to about 6.0
greater than about 2000 to about 4000.	from about 50 to about 100	from about 20 to about 36	from about 0.2 to about 6.0

26. The braided suture of claim 25 wherein for a given overall suture denier, the range of pick count, number of sheath yarns and denier of individual filaments comprising a sheath yarn are related to each other as follows:

Overall Suture Denier	Pick Count	Number of Sheath Yarns	Denier of Individual Filaments
greater than about 300 to about 500	from about 55 to about 80	from about 12 to about 14	from about 0.8 to about 3.0
greater than about 500 to about 800	from about 55 to about 80	from about 14 to about 18	from about 0.8 to about 3.0
greater than about 800 to about 1200	from about 55 to about 80	from about 20 to about 30	from about 0.8 to about 3.0
greater than about 1200 to about 2000	from about 55 to about 80	from about 24 to about 34	from about 0.8 to about 3.0

27. The braided suture of claim 26 possessing a core.

28. The braided suture of claim 27 wherein the individual filaments are fabricated from a bio-absorbable polymer.

29. The braided suture of claim 28 wherein the individual filaments are fabricated in whole or in part from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

13

30. The braided suture of claim 26 wherein the individual filaments are fabricated from a bio-absorbable polymer.

31. The braided suture of claim 30 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

32. The braided suture of claim 25 possessing a core.

33. The braided suture of claim 25 wherein the overall suture denier and core denier are related to each other as follows:

Overall Suture Denier	Denier of Core
greater than about 300 to about 500	from about 80 to about 150
greater than about 500 to about 800	from about 150 to about 300
greater than about 800 to about 1200	from about 250 to about 700
greater than about 1200 to about 2000	from about 400 to about 1200
greater than about 2000 to about 4000.	from about 800 to about 2400

34. The braided suture of claim 27 wherein the overall suture denier and core denier are related to each other as follows:

Overall Suture Denier	Denier of Core
greater than about 300 to about 500	from about 80 to about 120
greater than about 500 to about 800	from about 180 to about 280
greater than about 800 to about 1200	from about 350 to about 650
reater than about 1200 to about 2000	from about 500 to about 1000
greater than about 2000 to about 4000.	from about 1000 to about 2200

35. The braided suture of claim 34 wherein the individual filaments are fabricated from a bio-absorbable polymer.

36. The braided suture of claim 35 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected

14

from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

37. The braided suture of claim 32 wherein the individual filaments are fabricated from a bio-absorbable polymer.

38. The braided suture of claim 37 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

39. The braided suture of claim 33 wherein the individual filaments are fabricated from a bio-absorbable polymer.

40. The braided suture of claim 39 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

41. The braided suture of claim 25 wherein the individual filaments are fabricated from a non-absorbable material.

42. The braided suture of claim 41 wherein the non-absorbable material is cotton, silk, polyamide or polyolefin.

43. The braided suture of claim 25 wherein the individual filaments are fabricated from a bio-absorbable polymer.

44. The braided suture of claim 43 wherein the individual filaments are fabricated from a polymer derived at least in part from one or more monomers selected from the group consisting of glycolic acid, glycolide, lactic acid and lactide.

45. The braided suture of claim 25 surface coated with a composition enhancing one or more functional properties of the suture.

46. The braided suture of claim 25 containing at least one medico-surgically useful substance.

47. The braided suture of claim 25 containing at least one growth factor.

48. The braided suture of claim 25 containing at least one growth factor selected from the group consisting of fibroblast growth factor, bone growth factor, epidermal growth factor, platelet derived growth factor, macrophage derived growth factor, alveolar derived growth factor, monocyte derived growth factor and magainin.

* * * * *

50

55

60

65

EXHIBIT 46

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation
Plaintiff,
v.
Arthrex, Inc.
a Delaware Corporation and
Pearsalls Ltd.
a Private Limited Company of
the United Kingdom
Defendants.

Civil No. 04-12457 PBS

DePuy Mitek's Supplemental Responses To Arthrex, Inc.'s Interrogatories

DePuy Mitek sets forth both its original responses and its supplemental responses below.
Each supplemental response is intended to incorporate in its entirety the original response,
including any objections.

Interrogatory No. 2

For each claim of the '446 Patent identified in response to Interrogatory No. 1, state the basis for DePuy Mitek's (as defined above) contention of infringement separately with respect to each and every product of Arthrex accused of infringement, including a claim chart explaining DePuy Mitek's contention as to how each element of each claim being asserted is met by each specific Arthrex product, whether such alleged infringement is literal or under the doctrine of equivalents, identify any and all documents on which DePuy Mitek relies to support its response to this interrogatory and identify the three individuals currently and/or formerly within DePuy Mitek's employ who are believed to be the most knowledgeable with respect to the subject matter of this interrogatory.

Response to Interrogatory No. 2

DePuy Mitek objects to this interrogatory to the extent that it demands information that is immune from discovery on the basis of the attorney-client privilege, the work-product doctrine, or Rule 26(b)(4)(B) immunity.

DePuy Mitek further objects to this interrogatory as premature because discovery has just begun, and DePuy Mitek has not yet received sufficient information from Arthrex to answer this interrogatory with the specificity that Arthrex seeks.

Patent at 3:50, 65-66) in which the second and third fiber sets 11, 13 “are helically-disposed” and “oriented at substantially the same acute braiding angle A” (*id.* at 4:1-5). According to the 688 Patent, the fibers 9 are “straight” and oriented in “the longitudinal direction” (*id.* 3:64-4:1) and are not in a “braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set,” as claimed.

The 688 Patent also does not disclose the claimed “first-fiber forming material” or the claimed “second fiber-forming material.” Rather, in the 688 Patent, the fibers are “identical” or of the same material (*id.* at 5:48-49, Table in Columns 5-6, Example 1 at 8:51-57; Example 2 at 9:15-17). Thus, the second and third fibers sets 11, 13 are not the claimed “first fiber-forming material” nor the claimed “second fiber-forming material” because they are not the different claimed materials.

Claim 1 would not have been obvious in view of the 688 Patent combined with either the 983 Patent, U.S. patent No. 3,942,532, or both the 983 and 400 Patents to form the claimed invention because there are significant differences between what is disclosed in those patents and what is claimed in the 466 Patent. For example, as noted above, the 688 Patent discloses ligament prosthesis and not a heterogeneous braided suture. But even if the patents were properly combinable, Arthrex has not pointed to any motivation to combine a ligament reference with any of the other references in a manner that a person skilled in the art would come up with the claimed suture. Arthrex’s so-called motivation is unsupported attorney assertions based on improper hindsight. Further, the sales of Arthrex’s FiberWire products are evidence of commercial success of the claimed invention and is evidence of the claimed invention’s nonobviousness.

Claim 2 is nonobvious over the 688 and 983 Patents and the alleged “state of the art” and U.S. Patent No. 3,454,011 for at least the reasons set forth above with respect to the 688 and 983 Patents.

Claim 8 is nonobvious over the 688 patent for at least the same reasons as stated above. It is Arthrex’s burden to show that the claimed invention is obvious by clear and convincing evidence. Because Arthrex has not explained its contentions with respect to the 688 Patent and claim 8, DePuy Mitek is unable to respond with any further detail.

Claim 12 is nonobvious over the 688 Patent for the reasons set forth above with respect to claims 1, 2, and 8.

Claims 1, 2, 8 and 12 are not anticipated by U.S. Patent No. 5,318,575. The 575 Patent is not prior art to claims 1, 2, 8, and 12 of the 446 Patent because these claims were conceived and reduced to practice before the date on which the application that matured into the 575 Patent was filed – February 3, 1992 (DePuy Mitek’s Res. To Arthrex’s Int. No. 6). Further, Arthrex’s contentions are deficient and do not recite a *prima facie* anticipation of any of claims 1, 2, 8, or 12 because Arthrex has failed to cite to a teaching of braided yarns as claimed in the Hunter Patent.

In addition, Arthrex's contentions are deficient because Arthrex fails to explain how the 575 Patent teaches each and every element of the claimed heterogeneous braided suture.

Claims 1 and 8 are not invalid under 35 U.S.C. §103 over U.K. Patent Application No. 2,218312A (Burgess) in view of the state of the art at the time of the invention or the 983 Patent.

Claims 2 and 12 are not invalid over Burgess in view of the 011 Patent. As Arthrex admits, Burgess discloses a fishing line, not a medical device, or a suture. Further, Burgess was before the Patent Office during the prosecution of the Hunter Patent. It would not have been obvious to combine Burgess with the 983 Patent to form the invention of claims 1 and 8 or the invention of claims 2 and 12 for several reasons.

For example, there are differences between the claimed inventions and Burgess and the 983 Patent, as discussed above. Further, there is no motivation or suggestion to combine the references in a manner such that one of ordinary skill in the art would arrive at the claimed invention. Arthrex's contentions regarding combining these references are based on unsupported attorney assertions and improper hindsight. Also, Arthrex's FiberWire sales are evidence of the commercial success of the claimed invention and the nonobviousness of the claimed invention.

The claims of the 446 Patent are enabled. Arthrex incorrectly asserts that the 446 Patent "does not enable one skilled in the art to make and use a surgical suture that requires a coating in order to achieve enhanced characteristics of the braid, such as pliability or handleability of the suture without significantly sacrificing its physical properties (such as suture strength, knot strength and security, etc.)." Arthrex's contention fails to state a legal reason for contesting enablement. Although not agreeing that Hunter was required to show enablement for a non-claimed coating, the patent specification expressly teaches a suture having a coating (e.g., 446 Patent at 6:5-17). It is also within the knowledge of persons skilled in the art how to coat a suture.

Arthrex also incorrectly contends that the claims are not enabled because it incorrectly alleges that the 446 Patent specification does not enable one of ordinary skill in the art to make and use a yarn from the first set of disclosed yarns to provide strength and the second set to provide pliability. Again, Arthrex's contention fails to state a legally cognizable enablement defense. To the extent DePuy Mitek understands Arthrex's contentions, the 446 Patent specification teaches one skilled in the art to make and use a yarn from the first and second set of disclosed materials and to have the properties of such a braid. For example, certain materials are disclosed, (e.g., 446 Patent at 4:9-40) and braiding the yarns is disclosed (e.g., 446 Patent at 4:41-6: 4). Given the teachings of the 446 Patent, one skilled in the art could have made and used a braided yarn from the first set of claimed materials and the second set of claimed materials.

Arthrex further incorrectly contends that the phrase "consisting essentially of" is construed such that claim 1 covers FiberWire, then claim 1 is indefinite. Arthrex has failed to provide an explanation of why the term or the claim would be indefinite. Thus, DePuy Mitek cannot respond to Arthrex's conclusory assertion except to state that the claim is presumed definite under 35 U.S.C. §282.

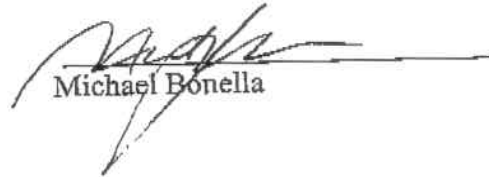
CERTIFICATE OF SERVICE

I certify that the foregoing DePuy Mitck's Supplemental Responses To Arthrex, Inc.'s Interrogatories was served by facsimile on February 24, 2006 on the following:

Charles W. Saber
Dickstein, Shapiro, Morin & Ochinsky, LLP
2101 L. Street, NW
Washington, DC 20037-1526.
Fax: (202) 887-0689

Christopher Weld, Jr.
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
Fax: (617) 227-5777

Dated: February 24, 2006


Michael Bonella